EXHIBIT A

Expert Report of John Flack, M.D., M.P.H.

I. Nature and Purpose of Report and Disclosures

This report is being offered pursuant to Federal Rule of Civil Procedure 26. Each of the opinions I have offered in this report is given to a reasonable degree of medical and scientific certainty. Additionally, each of my opinions is based on the materials I have reviewed in connection with this litigation, the methods and procedures of science, my knowledge of recognized medical and scientific principles and methodology reasonably relied upon by members of my profession, as well as my education, training, knowledge, and experience. Each opinion is offered to articulate a sufficiently reliable basis for my opinions concerning this case.

My curriculum vitae is attached as Exhibit A to this report. During the previous 4 years, I did not testify as an expert at trial or in a deposition outside of this litigation. My fees charged in connection with this engagement are consistent with my normal practice for such work. My work reviewing materials and preparing this report has been billed at $600 per hour. My hourly rate for deposition and trial testimony is $850.

A list of materials that I considered in rendering the opinions offered in this report is attached as Exhibit B. I reserve the right to supplement this list, as well as to amend and supplement the opinions expressed in this report. I also reserve the right to respond to and rebut all information provided in discovery, which I understand is ongoing, and any opinions offered by Plaintiffs' experts at their depositions or at trial.

Citations to specific reference material also are offered in this report, where I believe it necessary to cite a specific source; otherwise, my opinions are derived from a combination of reference sources, my experience, training, education and knowledge in the field. The facts and data set forth herein are the types of facts and data that I and other experts in my field reasonably rely upon. This report is not meant to be an exhaustive recitation of all my opinions as I understand they will be more fully explored in my deposition.[1]

I have been asked on behalf of Defendants to provide an independent analysis of whether trace amounts of N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA") found in valsartan products could increase the risk of cancer in hypertension patients, such as Plaintiffs. I will offer opinions on hypertension generally, including its diagnosis and treatment, risk factors, epidemiology, secondary causes, and comorbidities, all of which relate to the underlying questions of causation. These opinions will include opinions on hypertension drug therapy, including use of valsartan, and the background of the valsartan recall. Additionally, I will opine on the epidemiology of hypertension and cancer, including the increased incidence of cancer in hypertension patients. I will also offer opinions on the medical and scientific literature on NDMA/NDEA and cancer, as well as valsartan and cancer, and Plaintiffs' claims of developing cancer allegedly as a result of using valsartan.

[1] This report is intended to offer opinions regarding general causation only, as requested by counsel. This report is not intended to be an exhaustive recitation of all of my opinions in this litigation, and I expressly reserve the right to amend or supplement this report to offer additional opinions, including opinions on liability, specific causation, damages, or other defenses, at the appropriate stage of litigation.

I have independently conducted a review and analysis of the literature on the above-listed topics, including in particular, but not limited to, the background risk factors for cancer in hypertension patients, the association between NDMA/NDEA and cancer, and the alleged relationship between valsartan use and cancer. In my regular practice and for purposes of my publications, I regularly research and analyze medical and scientific literature and rely on my education, training, and experience in the fields of internal medicine as well as epidemiology to form well-reasoned conclusions based on the available literature. I applied that same process to review and analyze the medical and scientific literature in this case.

I reserve the right to modify this report and my opinions as additional information is provided, including but not limited to additional discovery, medical records, expert reports, and the depositions of fact and expert witnesses.

II. Professional Education, Background and Accomplishments

I have served as the Professor and Chair of the Department of Internal Medicine at Southern Illinois University (SIU) for the past 6 years. I am also the Sergio Rabinovich Endowed Chair of Internal Medicine and Chief of the Hypertension Section in the Division of General Internal Medicine at SIU where I teach, conduct hypertension research, have an active hypertension clinical practice and lead the Department of Medicine (~50 million dollar annual budget). I am President of the American Hypertension Specialist Certification Program, serve as one of four Associate Editors at the American Journal of Hypertension, and chair the American Heart Association (AHA) Hypertension Professional Education and Publications Committee. I have published ~210 peer-reviewed manuscripts/book chapters and

my work has been cited over 14,000 times (Mendley Statistics). I have lifetime certification in Internal Medicine from the American Board of Internal Medicine (ABIM) as well as lifetime certification as a Specialist in Clinical Hypertension from the American Society of Hypertension.

In 1978, I earned a BS degree in Chemistry (Math minor) with distinction from Langston University. I subsequently entered the University of Oklahoma School of Medicine, graduating in 1982 with an MD degree; during medical school, I was elected to the Alpha Omega Alpha (AOA) Medical Honor Society. After graduation from medical school, I immediately entered the University of Oklahoma Internal Medicine residency training program that I completed in 1985; in 1985-86, I served as Chief Medical Resident for this training program. After two years as an Instructor on the University of Oklahoma Department of Medicine faculty, I left for the University of Minnesota School of Public Health, Division of Epidemiology where I completed a two-year National Institutes of Health post-doctoral fellowship in Cardiovascular Epidemiology. In 1990, I also earned a Master of Public Health (MPH) degree in Epidemiology from the University of Minnesota.

Throughout my career I have received numerous honors, served on various committees, and have provided professional service relevant to my expertise in hypertension and clinical trials. I served a multi-year term as a standing member of the U.S. Food and Drug Administration ("FDA") Cardio-Renal Advisory Panel and serve as an ad hoc reviewer for over 50 peer-reviewed medical journals (e.g., Hypertension [premier hypertension journal in the world], Journal of American Medical Association [JAMA], Journal of the American Society of Hypertension [JASH], Mayo Clinic Proceedings). I have also received numerous awards in my career, such

as being selected as one of the Detroit Super Doctors (2014), and repeatedly selected as one of the "Best Doctors in America", Michiganian of the Year (Detroit News, 2009), Academic Physician of the Year from the University of Oklahoma School of Medicine (2012), the American Heart Association F. Dewey Dodrill Award for Excellence (2007), and Crain's Detroit Business Health Care Hero Award for Outstanding Physician Achievement (2005).

Finally, I was asked and accepted an invitation to author the next *Hypertension* book chapter for the renowned Cecil's Textbook of Medicine. I am also currently authoring the chapter on *Initial Selection of Antihypertensive Drugs* for Up-to-Date (a recognized medical reference source used around the world). I have been recognized as an international expert and leading authority in hypertension.

A more detailed description of my academic and professional background and qualifications may be found in my curriculum vitae attached as Exhibit A.

III. Materials Reviewed

In my practice, I continuously review relevant medical literature as it is published, and as clinical issues come up that require re-review. The facts and data set forth below are of the type that I and other experts in my field reasonably rely upon. Many of my opinions expressed in this report are based on my cumulative knowledge from many years of hypertension practice and the literature I have reviewed over that time and on information I believe is generally known and accepted as true by those practicing in the hypertension community. During this engagement, I have reviewed the materials identified in Exhibit B.

IV. Definitions

ACE Inhibitor Angiotensin Converting Enzyme Inhibitor

ARB Angiotensin Receptor Blocker

ARNI Angiotensin Receptor Neprilysin Inhibitor

AHA American Heart Association

AMA American Medical Association

AOA Alpha Omega Alpha Medical Honor Society

ARNI Angiotensin Receptor Neprilysin Inhibitor (valsartan/saccabutril)

BS Bachelor of Science

BP blood pressure

DBP diastolic blood pressure

dl deciliter

eGFR estimated glomerular filtration rate

FMD fibromuscular dysplasia

mg milligrams

mm Hg millimeters of mercury

MD Medical Doctor

Meta-analysis a group of clinical trials that have been combined together and analyzed as a single study

PP pulse pressure (SBP – DBP)

SBP systolic blood pressure

SIU Southern Illinois University School of Medicine

SMR Standardized Mortality Ratio

≥ Equal to or greater than

≤ Equal to or less than

V. Hypertension Generally

A. What Is Hypertension?

Hypertension, or elevated blood pressure, occurs when the pressure inside the arterial blood vessels consistently exceeds 130/80 mmm Hg. Indirect estimation of the blood pressure level is most commonly done by applying an appropriate size blood pressure cuff over a bare arm (just above the elbow) to compress the brachial artery which stops the normal continuous flow of blood. The cuff is deflated slowly and when the external pressure falls below the blood pressure in the brachial artery, the return of pulsating sound (Korotkoff sounds) marks the level of systolic BP. At this point, the flow of blood in the brachial artery is episodic, not continuous. As the BP cuff further deflates, the flow of blood in the brachial artery ultimately becomes continuous at which point the Korotkoff sounds disappear – this marks the level of diastolic blood pressure. Thus, every individual has a systolic (top number) and diastolic blood pressure (bottom number) – for example, 120/80 mm Hg.

B. Blood Pressure Classifications/Stages of Hypertension

The 2017 American College of Cardiology (ACC)/American Hypertension Association (AHA) hypertension guideline[2] revised how we classify blood pressure levels. *Normal* is considered to be less than 120 systolic and less than 80 mm Hg diastolic; *Elevated* is when systolic blood pressure is between 120 – 129 and diastolic blood pressure is less than 80 mm Hg; *Stage 1 hypertension* is when systolic blood

[2] Whelton PK et al., 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension 2018;71:e13-e115.

pressure is 130 – 139 and diastolic blood pressure is 80 – 89 mm Hg; and *Stage 2 hypertension* is when systolic blood pressure is 140 or higher and diastolic blood pressure is 90 mm hg or higher. When the systolic and diastolic blood pressures fall into different categories, the highest category determines the blood pressure classification or stage of hypertension. BP 138/110 mmm Hg, for example, would be stage 2 hypertension.

Blood pressure categories and stages of hypertension have therapeutic significance. In adults with elevated, stage 1, or stage 2 hypertension, lifestyle modifications (weight loss, sodium and alcohol restriction, and physical activity increase) should be provided. And though hypertension is diagnosed when blood pressure exceeds the 130/80 mm Hg threshold, only high-risk hypertensives actually qualify for drug therapy in stage 1 hypertension; the majority (~70%) of all hypertensives do not qualify for drug therapy until they reach stage 2 hypertension.[3]

C. Hypertension Risk Factors

Hypertension risk factors include obesity/rapid weight gain, physical inactivity, excessive alcohol intake (> 2 drinks/d in men, > 1 drink/d in women), and high dietary sodium intake. Accordingly, weight loss, increased physical activity, reductions in alcohol intake, and decreased intake of dietary sodium have been shown to lower blood pressure. The ACC/AHA hypertension guideline recommends

[3] Muntner P et al., Potential US population impact of the 2017 ACC/AHA high blood pressure guideline, Circulation 2018;137(2):109-118.

counseling on diet and lifestyle modifications for all adults with elevated blood pressure (SBP 120 – 129 and DBP less than 80 mm Hg) and hypertension.[4]

D. Epidemiology of Hypertension

According to the AHA/ACC 2017 hypertension guideline ~116 million US adults or 45.6% of the adult population age 20 years and older have hypertension.[5] Importantly, this guideline—for the first time—used the BP threshold of 130 (systolic) and/or 80 mm Hg (diastolic) as the level above which drug naïve individuals would be diagnosed as having hypertension; up until late 2017, the diagnostic BP threshold for hypertension had been 140/90 mm Hg. SBP rises with advancing age while DBP plateaus in the 6th decade of life and, on average, declines thereafter; this leads to wide pulse pressure hypertension that most commonly occurs amongst older hypertensives. Women are more frequently affected by hypertension than men. The highest geographic prevalence of hypertension in the US is in the southeastern geographical area, also known as the stroke belt. 54.9%, 47.3%, 34.4%, and 36.5%, respectively, of Non-Hispanic blacks, Non-Hispanic whites, Hispanics, and Non-Hispanic Asians have hypertension.[6]

[4] Whelton PK et al., 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension 2018;71:e13-e115.
[5] *Id.*; Muntner P et al., Potential US population impact of the 2017 ACC/aHA high blood pressure guideline, Circulation 2018;137(2):109-118.
[6] Whelton PK et al., 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension 2018;71:e13-e115.

E. Secondary Causes of Hypertension

The vast majority of adults with hypertension have essential hypertension. Essential hypertension refers to elevated blood pressure readings that are not directly linked to a specific known secondary cause. Major secondary causes of hypertension can manifest in persons who have previously had normal blood pressure, though when secondary causes occur in adults, especially beyond the mid 40's, they often occur super-imposed on essential hypertension.

Major causes of secondary hypertension include:

1) *Obstructive Sleep Apnea*: this condition is seen much more commonly in men than women and is the most common type of secondary hypertension. And though obesity is an important risk factor for this condition, sleep apnea can occur in lean individuals as well. Sleep apnea is characterized by intermittent upper airway obstruction that leads to sympathetic nervous system activation, fragmented sleep patterns, elevated blood pressure, and increased risk for cardiovascular disease. The gold standard treatment for sleep apnea is continuous positive airway pressure (CPAP), a device worn during sleep that helps prevent upper airway collapse and therefore the obstructions that characterize sleep apnea. Some patients with sleep apnea do not tolerate CPAP therapy so we recommend that they get fit for an oral appliance that pulls forward the lower jaw thus decreasing the likelihood of intermittent upper airway collapse during sleep.

2) *Primary Aldosteronism*: primary aldosteronism is the second most common cause of secondary hypertension. This condition is characterized by autonomous secretion of aldosterone from one or both adrenal glands that leads to salt and water

retention, constriction of blood vessels, elevated blood pressure and severe target-organ injury – left ventricular hypertrophy/heart failure, kidney dysfunction, stroke, and myocardial infarction (heart attack). The excessive, autonomous hyper-secretion of aldosterone occurs bilaterally in ~two-thirds of cases and unilaterally in the other one-third. Those with unilateral hypersecretion are typically candidates for laparoscopic adrenalectomy, a procedure that cures the hypertension in ~50% of patients. In those who are not cured after adrenalectomy, BP is typically lower and can be more easily controlled with fewer medications. Primary aldosteronism patients with bilateral hypersecretion of aldosterone are not surgical candidates and are therefore managed medically with stringent dietary sodium restriction, and antihypertensive drug therapy (thiazide diuretics, aldosterone antagonists, calcium antagonists, ACE inhibitors, ARBs).

3) Renal Artery Stenosis (Renovascular Hypertension): obstruction of one or both arteries leading to the kidneys, which if significant enough (termed critical renal artery stenosis) can cause elevated blood pressure and, if affecting both kidneys, can also cause kidney dysfunction. The most common cause of renal artery obstruction is the build-up of atherosclerotic plaque, although there are other uncommon causes of obstruction (e.g., renal artery dissection). Most patients with critical renal artery stenosis do not respond to renal revascularization (angioplasty + stenting) with any discernable improvement in blood pressure. Accordingly, based on the best available clinical trial evidence, the most recent ACC/AHA hypertension guideline does not recommend screening for critical renal artery stenosis except in patients with heart failure/recurrent flash pulmonary edema, refractory hypertension, and/or reduced/worsening kidney function (ischemic nephropathy). Another form of critical

renal artery stenosis is called fibromuscular dysplasia (FMD). FMD is, though, much less common than atherosclerotic renal artery stenosis. FMD preferentially affects women and does respond to angioplasty of the affected renal artery (without stenting) with prompt reductions in blood pressure. FMD is caused by an intrinsic renal artery abnormality that causes the vessel to intermittently narrow resulting in the classic "string of pearls" appearance of renal arterial angiograms. We infrequently pursue the diagnosis of critical renal artery stenosis except in the patient types as described in the ACC/AHA hypertension guideline.

4) Pheochromocytoma: this is a very rare but devastating form of secondary hypertension. The primary abnormality in pheochromocytoma is hypersecretion of catecholamines (norepinephrine, epinephrine, dopamine), typically from the adrenal gland(s) although occasionally the anatomic source of the hyper-secretion can be extra-adrenal in origin. Clinically patients have signs, at least intermittently, of sympathetic nervous system activation including spikes in blood pressure, very rapid heartbeat, sweating, and anxiety. Pheochromocytoma is rare. Untreated or inadequately treated obstructive sleep apnea can mimic pheochromocytoma as both conditions augment sympathetic nervous system activity and can cause similar clinical symptoms.

F. Hypertension Risk Stratification

The 2017 ACC/AHA hypertension guideline outlined a somewhat different approach to risk-stratifying hypertensive patients than was previously

recommended.[7] The basic premise of the new recommendation was that *high-risk* hypertensives would be treated sooner (at a lower blood pressure level) than lower risk hypertensives. The rationale for this recommendation was that meta-analyses of hypertension studies have shown that the absolute cardiovascular risk reduction was directly related to the magnitude of pre-treatment cardiovascular risk.[8] Pre-treatment cardiovascular risk is not solely a consequence of hypertension severity but is also related to the presence of certain co-morbidities as well as the presence of known cardiovascular disease. Thus, the greater cardiovascular risk reduction with drug therapy in *high-risk* hypertensives is the compelling reason for treating them sooner.

High-risk in individuals with hypertension is defined by the presence of at least of the following: 1) age 65 years or older; 2) known cardiovascular disease (e.g., heart failure, prior myocardial infarction or stroke); 3) diabetes mellitus; 4) chronic kidney disease (estimated glomerular filtration rate less than 60 ml/min/1.73 m^2 and/or urine albumin/creatinine ratio of 300 mg/g or greater or prior kidney transplant); or 5) 10-year atherosclerotic cardiovascular disease risk of 10% or higher.

Thus, high-risk hypertensives qualify for drug therapy when their blood pressure is 130/80 mmm Hg or higher; lower risk hypertensives qualify for drug

[7] Whelton PK et al., 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension 2018;71:e13-e115.

[8] van der Leeuw J et al., Personalized cardiovascular disease prevention by applying individualized prediction of treatment effects, Eur Heart J. 2014;35(13):837-843; Baker S et al., Using thresholds based on risk of cardiovascular disease to target treatment for hypertension: modelling events averted and number treated, BMJ, 2000;320(7236):680-685 [published correction appears in BMJ 2000 May 27;320(7247):1436].

therapy when their blood pressure is 140/90 mm Hg or higher. Most hypertensives, including both high- and low-risk individuals, are treated to a target of less than 130/80 mm Hg, although for individuals 65 years of age and older, only a systolic blood pressure target was given (less than 130 mm Hg).

G. Hypertension Control Rates

Nearly 82 million or 36.2% of US adults qualify for immediate antihypertensive drug therapy.[9] 53.4% of drug-treated hypertensive adults have BP $\geq$ 130/80 mm Hg.[10] Using the 140/90 mm Hg threshold, the hypertension control rate declined to 43.7% (2017 – 2018) from 53.8% (2013 – 2014).[11] BP control was highest in adults aged 45 – 64 years of age but was lower at both extremes of age. Controlled BP was documented in 48.2% of non-Hispanic Whites, versus 41.5% of non-Hispanic Blacks; control rates were also higher in those with private insurance (48.2%) and Medicare (53.4%) versus those with government insurance other than Medicare or Medicaid (43.2%).[12] Thus, hypertension control in the US population is sub-optimal and manifests significant disparities by race/ethnicity and insurance status.

H. Major Hypertension Outcomes

Hypertension is a major, treatable risk factor for premature death, stroke, heart failure, chronic kidney disease [CKD]/end-stage renal disease [ESRD], myocardial infarction, peripheral vascular disease, and dementia. These risks

[9] Muntner P et al., Potential US population impact of the 2017 ACC/AHA high blood pressure guideline, Circulation 2018;137(2):109-118.
[10] *Id.*
[11] Muntner P et al., Trends in Blood Pressure Control Among US Adults with Hypertension, 1999-2000 to 2017-2018, JAMA 2020;324(12):1190-1200.
[12] *Id.*

attributable to blood pressure elevations do not magically appear when the BP is high enough to be considered hypertension. Rather, there is a graded, continuously escalating risk of these outcomes that begins well within the normal range as BP increases above 115/75 mm Hg. This risk for adverse cardiovascular outcomes doubles for every 20/10 mm Hg higher BP above 115/75 mm Hg. Accordingly, not all adults at increased risk for the adverse health effects of hypertension are recommended for or undergoing antihypertensive drug therapy.

I. Hypertension Co-morbidities

In general, patients with hypertension are not as healthy as other people and often have comorbidities. Hypertension occurs commonly in persons with diabetes and chronic kidney disease. In fact, approximately 80% of adults with these two co-morbid conditions have hypertension. The coexistence of hypertension and diabetes occurs, in no small part, because of common risk factors such as obesity, physical inactivity, and a calorie-replete diet. Hypertension and chronic kidney disease occur together because not only is hypertension a risk factor for CKD but also, the more kidney function deteriorates, the greater likelihood of hypertension; this is likely due to the inability to maintain normal salt and water homeostasis as kidney function worsens in persons with sodium-replete diets. Persons with known cardiovascular disease (e.g., heart failure, stroke) often have hypertension because elevated BP is a known risk factor for most cardiovascular diseases.

Importantly, the presence of the above hypertension co-morbidities substantively impacts the recommended approach to antihypertensive treatment. First, diabetes, chronic kidney disease, and cardiovascular disease, when present in

hypertensives, place them in the high-risk category, meaning that they qualify for antihypertensive drug therapy when their BP is consistently at or above 130 systolic and/or 80 mm Hg diastolic. Second, these conditions have all been linked to pharmacological resistance to antihypertensive drug therapy, meaning that a greater intensity of drug therapy will be needed to achieve BP control. Third, the presence of selected co-morbidities in persons with hypertension impacts antihypertensive drug selection. For example, in those with CKD, ACE inhibitors or ARBs should be included in the antihypertensive drug treatment regimen because they have been proven to slow the progressive decline over time in kidney function. Amongst patients with heart failure, both those with reduced as well as preserved ejection fraction, ACE inhibitors or ARBs, along with beta blockers and aldosterone antagonists, reduce morbid and fatal events and are thus preferred therapies. New data with angiotensin receptor neprilysin inhibitors (ARNIs) have shown the superiority of this drug class relative to ACEs and ARBs in heart failure patients, both with reduced and preserved ejection fraction.

J. Diagnosing Hypertension

The diagnosis of hypertension is most commonly made when there are sustained blood pressure elevations that are documented over temporally spaced time points of measurement. Often, though not always, this occurs in a physician's office. The optimal approach is to use a standard measurement protocol, obtain multiple blood pressure readings to be averaged, and repeat this over time. The diagnosis of hypertension is made when blood pressure consistently is 130 and/or 80 mmm Hg or higher. Ideally, this should be the average of multiple blood pressure readings at each visit across multiple (at least 2) visits. The exception to this is when

blood pressure is 180 systolic and/or 110 mm Hg diastolic or higher, in which case the diagnosis of hypertension is confirmed and drug therapy should be started immediately.

K. Accurate BP Measurement

Accurate measurement of BP is imperative for making sound therapeutic decisions regarding antihypertensive drug therapy. However, accurate BP measurement in any setting does not occur without purposeful intent. First, validated BP devices should be used when taking BP. Second, a standard measurement protocol should be followed as summarized in the Target-BP program [quiet room/no conversation, empty bladder, use correct cuff size, place BP cuff on bare arm, support arm at heart level, keep legs uncrossed, and support back and feet.][13] Finally, multiple BP measurements should be obtained, spaced ~1 minute apart and averaged. Adherence to the aforementioned approach results in BP readings that are systematically lower than usual office BP readings. One study by Egan and colleagues reported an 11/5 mm Hg lower BP in uncontrolled hypertensives after implementing a rigorous BP measurement protocol in the absence of any changes to medications.[14]

Despite accurate measurement of BP being required for making sound diagnostic decisions, very few clinics utilize rigorous BP measurement protocols. The most likely explanation is that rigorous BP measurement protocols change workflow, as you cannot measure an accurate BP as quickly as you can a spuriously high one

[13] How to accurately measure blood pressure at home, www.heart.org, *available at* https://www.heart.org/en/news/2018/05/01/aha-ama-launch-high-blood-pressure-initiative (last accessed July 29, 2021).
[14] Egan BM et al., Improving Hypertension Control in Primary Care with the Measure Accurately, Act Rapidly, and Partner with Patients Protocol, Hypertension 2018;72(6):1320-1327.

obtained by usual means. However, there are multiple benefits when BP is measured accurately: 1) hypertension is not spuriously diagnosed; 2) hypertension severity is not overestimated; 3) white coat hypertension/effect is minimized; 4) over-medication of patients is avoided; and 5) in-office BP control rates are substantively higher.

L. Initial Patient Evaluation

The ACC/AHA hypertension guideline provides excellent guidance regarding the initial patient evaluation for patients with hypertension.[15] First and foremost, every patient should have a comprehensive history and physical examination performed. Examples of important history to obtain include the duration of hypertension, medication history, the range of blood pressure levels since diagnosis, dietary patterns, physical activity, alcohol intake, snoring/the presence of daytime sleepiness, history of low potassium level, all medications (prescribed as well as those drugs obtained over the counter), family history of early onset hypertension in first degree relatives (before 25 years of age) and/or stroke (before 40 years of age). Available medical records, including clinic notes, laboratory and diagnostic tests should be reviewed. At the initial visit, multiple blood pressure readings should be obtained (1 minute apart) and averaged in both arms as well as in both the seated and standing positions (checking for orthostatic hypotension). The arm with the

[15] Whelton PK et al., 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension 2018;71:e13-e115.

highest averaged BP reading should be used for BP measurements at subsequent clinic visits.

Recommended basic testing includes: 1) fasting blood glucose, 2) complete blood count, 3) lipid profile, 4) serum creatinine with eGFR, 5) serum sodium, potassium and calcium, 6) thyroid stimulating hormone, 7) urinalysis, and 8) electrocardiogram. Optional testing includes: 1) echocardiogram, 2) uric acid, and 3) urinary albumin:creatinine ratio. In my clinical practice, I typically obtain a hemoglobin A1C in every patient as this allows the diagnosis of pre-diabetes and diabetes without the need for fasting – this is a better test than fasting glucose for making these diagnoses. Also, I measure uric acid and urine albumin:creatinine ratio in all patients with hypertension at their initial evaluation. The rationale is that there is considerable evidence of a BP lowering effect of allopurinol, a xanthine oxidase inhibitor that lowers serum uric acid, when given to individuals with serum uric acid > 5.5 mg/dl. And, there is good evidence that allopurinol reduces risk for stroke and myocardial infarction and also slows/prevents the decline in kidney function in patients with depressed kidney function. Thus, I frequently prescribe allopurinol to my patients with hypertension when their serum uric acid is 5.5 mg/dl or higher. Finally, the urine albumin:crea ratio (measured in a spot urine) is needed to determine if chronic kidney disease is present in patients with eGFR $\geq$ 60 ml/min/1.73 m^2, and, in patients with known CKD, when this ratio is $\geq$ 300 mg/d, an ACE inhibitor or ARB should be included preferentially in the antihypertensive drug regimen.

M. Patient Counseling

In diagnosing and treating hypertensive patients, I regularly counsel patients on the following topics:

Hypertension Disease Conditions/Symptoms: I always counsel patients regarding why their hypertension is being treated. That is, to prevent premature mortality as well as to reduce the risk for heart failure, stroke, myocardial infarction, peripheral arterial disease, kidney dysfunction/failure, and cognitive decline/dementia. And though hypertension has been labeled the "silent killer", it does cause side effects in some patients. For example, it is well known and accepted that headache can occur as a consequence of elevated BP. However, hypertension has also been linked to sleep disturbance and shortness of breath.[16] The BP number is important: the higher the BP, the higher the risk for these complications and also the greater the absolute risk benefit from successful drug therapy.

Diet and Lifestyle Changes: I also discuss what the patient can do with their diet and lifestyle, along with taking their prescribed medications, to lower their BP. The greater adoption of effective and lifestyle interventions, the more effective antihypertensive drug therapy will be or the less intensive drug treatment will need to be to achieve target BP levels. Although dieticians are available in ambulatory and hospital settings, in ambulatory clinic settings patients may never be referred to a

[16] Flack JM et al., The rapidity of drug dose escalation influences blood pressure response and adverse effects burden in patients with hypertension: the Quinapril Titration Interval Management Evaluation (ATIME) Study, ATIME Research Group, Arch Intern Med. 2000;160(12):1842-1847.

dietician by the provider or, if referred, may not attend scheduled sessions if their insurance plan does not cover it.

Dietary Sodium Restriction: sodium is widely present in a typical western society diet in amounts far above what is needed to meet physiological needs. The average American adult consumes ~3400 mg (3.4 grams or 148 mmols of sodium per day). High dietary sodium intake antagonizes the pharmacologic BP reductions attainable with most antihypertensive drug classes. There is no credible evidence that lowering dietary sodium intake, even drastically, harms patients. Current recommendations for daily dietary sodium intake range from 1500 mg (65.2 mmol) to 2500 mg (109 mmol) per day. Approximately 70 – 75% of dietary sodium is processed into the foods we eat prior to consumption. The following are common examples of high sodium foods: breads, soups, processed meats (e.g., bacon, salami, ham, sausage), fast foods, pickles, pizza, and frozen dinners.

Other Lifestyle Modifications: Certain lifestyle modifications proven to lower BP include the following: 1) limiting alcohol intake to no more than 2 drinks per day in men and no more than 1 drink per day in women, 2) weight loss, 3) increased physical activity (especially aerobic activity), 4) increased dietary consumption of potassium, and 5) increased consumption of vegetable protein.

Medication Adherence and Risks/Benefits: Another important conversation I have with patients is regarding adherence to the medications they have been prescribed. Studies have shown that at least 20% of patients never start taking

newly initiated hypertensive medications,[17] and of those who do start taking their medication, approximately 50% have stopped taking them within a year[18]. Antihypertensive medications have to be taken continuously to effectively lower BP. I also warn patients when taking certain drugs (e.g., beta blockers, central adrenergic inhibitors) that if they abruptly stop them, that they might conceivably experience a dangerous, dramatic rise in BP (rebound hypertension). Further, we counsel patients to avoid conflating hypertension condition/treatment symptoms with true adverse drug effects.

We also discuss with patients the risks and benefits of the prescribed antihypertensive medication. The primary benefits of an antihypertensive drug regimen include lowering BP and thus lowering the risk of suffering the major hypertension outcomes identified above (i.e., premature death, stroke, heart failure, chronic kidney disease [CKD]/end-stage renal disease [ESRD], myocardial infarction, peripheral vascular disease, and dementia). The risks, or potential side effects, associated with antihypertensive drugs are dependent on the particular drug prescribed but often include minor side effects, such as skin photosensitization and muscle cramps (thiazide diuretics); fatigue (beta blockers); dry non-productive cough (ACE inhibitors); lower extremity edema (dihydropyridine calcium antagonists) and even potentially severe side effects such as angioedema (ACE inhibitors) and skin cancer (thiazide diuretics).

[17] Fischer MA et al., Trouble getting started: predictors of primary medication nonadherence, Am J Med. 2011;124(11):1081.e9-1081.e1.081E22.
[18] Vrijens B et al., Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories, BMJ 2008;336(7653):1114-1117.

N. Hypertension Drug Therapy

Antihypertensive Drugs Generally: When patients qualify for antihypertensive drug therapy for the first time, there are several decisions that must be made. First, how many antihypertensive drugs will be prescribed? According the ACC/AHA hypertension guideline, the choice is either one or two drugs – prescribed as two separate pills or as a single pill combination.[19] It is recommended that two drug therapy be initiated in those with BP > 20/10 mm Hg above their target (typically <130/80 mm Hg), in most black patients, and should also be considered in patients with stage 2 hypertension (SBP $\geq$ 140 and/or DBP $\geq$ 90 mmm Hg). Fewer than 25% of drug-treated adult hypertensives within the USA are treated with more than 2 antihypertensive drugs.[20] Second, from which drug classes should initial drug therapy be selected? The ACC/AHA guideline recommends four initial drug classes as appropriate for initial therapy: 1) thiazide diuretics, 2) ACE inhibitors, 3) ARBs, and 4) calcium antagonists. The most effective two-drug combinations are either an ACE inhibitor or ARB + thiazide diuretic, or an ACE inhibitor or ARB + calcium antagonist. Once drug therapy has been initiated, patients should be evaluated approximately monthly for up-titration of their drugs if their BP remains above goal. Patients started on a thiazide diuretic and/or either an ACE inhibitor or ARB are often seen within a couple of weeks of starting treatment to check their serum electrolytes (e.g., serum sodium, potassium) and kidney function (creatinine, eGFR), both of

[19] Whelton PK et al., 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension 2018;71:e13-e115.
[20] Derington CG et al., Trends in Antihypertensive Medication Monotherapy and Combination Use Among US Adults, National Health and Nutrition Examination Survey 2005-2016, Hypertension 2020;75(4):973-981.

which can be adversely impacted by these two drug classes. However, long-acting antihypertensive drugs with long therapeutic half-lives take many weeks to manifest their full BP lowering effect, thus the recommendation is to intensify antihypertensive drug therapy, in most patients, no more frequently than approximately monthly. Once hypertension is controlled patients should be seen again every 3 – 6 months.

Role of Angiotensin Receptor Blockers in Contemporary Antihypertensive Drug Therapy: As of the publication of the ACC/AHA hypertension guideline in early 2018, there were 8 different ARBs and 10 ACE inhibitors approved by the FDA for the treatment of hypertension in the USA. ARBs and ACE inhibitors are considered mostly interchangeable as it relates to their benefits in heart failure (reduced ejection fraction) and chronic kidney disease (CKD), two conditions for which both drug classes have proven clinical benefit that is not solely explained by their ability to lower BP. Nevertheless, there are differences between these two drug classes that mostly relate to drug-related side effects. Angiotensin receptor antagonists (ARBs) have a tolerability profile comparable to placebo. Notably, ARBs do not have dose-related side effects (more side effects at higher doses).[21] Valsartan, losartan, and irbesartan are ARBs. ACE inhibitors, on the other hand, can cause angioedema and cough, while ARBs do not. ARBs and ACE inhibitors lower BP to a similar degree. ARBs as a drug class have previously been linked to an increase in risk for cancer;

[21] Pool JL et al., Dose-response efficacy of valsartan, a new angiotensin II receptor blocker, J. Hum. Hypertens. 1999;13(4):275-281; Brunner HR, Clinical efficacy and tolerability of Olmesartan. Clin. Ther. 2004;26 Suppl A:A28-A32.

however, this link was ultimately rejected by the FDA based on an extensive evaluation of clinical trial and observational data.[22]

O. Epidemiology of Hypertension and Cancer

Case-control and cohort studies[23] have reported higher incidence of cancer risk amongst hypertensives, both medicated[24] and un-medicated,[25] across varied cell-types (e.g., squamous cell carcinoma, adenoma carcinoma). BP level has been linked to increased risk of some cancers, including kidney cancer.[26] In addition, obese hypertensives have an augmented risk for kidney cancer compared to lean (BMI < 23) hypertensives.[27]

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[22] Sipahi I et al., Angiotensin-receptor blockade and risk of cancer: meta-analysis of randomised controlled trials, Lancet Oncol. 2010;11(7):627-636; Bangalore S et al., Antihypertensive drugs and risk of cancer: network meta-analyses and trial sequential analyses of 324,168 participants from randomised trials, Lancet Oncol. 2011;12(1):65-82; ARB Trialists Collaboration. Effects of telmisartan, irbesartan, valsartan, candesartan, and losartan on cancers in 15 trials enrolling 138,769 individuals, J Hypertens. 2011;29(4):623-635; Pasternak B et al., Use of angiotensin receptor blockers and the risk of cancer, Circulation 2011;123(16):1729-1736.

[23] Colt JS et al., Hypertension and risk of renal cell carcinoma among white and black Americans, Epidemiology 2011;22(6):797-804; Han H et al., Hypertension and breast cancer risk: a systematic review and meta-analysis, Sci Rep. 2017;7:44877; Hidayat K et al., Blood pressure and kidney cancer risk: meta-analysis of prospective studies, J Hypertens. 2017;35(7):1333-1344; Largent JA et al., Hypertension, diuretics and breast cancer risk. J Hum Hypertens. 2006;20(10):727-732; Seretis A et al., Association between blood pressure and risk of cancer development: a systematic review and meta-analysis of observational studies, Sci Rep. 2019;9(1):8565.

[24] Colt JS et al., Hypertension and risk of renal cell carcinoma among white and black Americans, Epidemiology 2011;22(6):797-804; Largent JA et al., Hypertension, diuretics and breast cancer risk, J. Hum. Hypertens. 2006;20(10):727-732; Seretis A et al., Association between blood pressure and risk of cancer development: a systematic review and meta-analysis of observational studies, Sci Rep. 2019;9(1):8565.

[25] Kim CS et al., Association of hypertension and blood pressure with kidney cancer risk: A nationwide population-based cohort study, Hypertension 2020;75:1439-1446; Chow WH et al., Obesity, hypertension, and the risk of kidney cancer in men, N. Engl. J. Med. 2000;343:1305-1311.

[26] Colt JS et al., Hypertension and risk of renal cell carcinoma among white and black Americans, Epidemiology 2011;22(6):797-804; Hidayat K et al., Blood pressure and kidney cancer risk: meta-analysis of prospective studies, J Hypertens. 2017;35(7):1333-1344.

[27] Kim CS et al., Association of hypertension and blood pressure with kidney cancer risk: A nationwide population-based cohort study, Hypertension 2020;75:1439-1446; Chow WH et

A recently published study by Christakoudi and co-workers from the European Prospective Investigation into Cancer and Nutrition (EPIC) involving over 300,000 men and women followed for an average of 13.7 years found positive associations between higher BP with renal cell carcinoma and esophageal squamous cell carcinoma as well as weaker associations with head and neck cancers, skin squamous cell carcinoma, colon cancer, post-menopausal breast cancer and uterine adenocarcinoma.[28] They also reported weak inverse associations of SBP with lymphomas and cervical squamous cell cancer.[29]

Additionally, some site-specific cancers may be increased such as kidney cancer along with, in women, pancreatic and endometrial cancers.[30] Lung cancer risk appears to be lower in hypertensives[31] while liver cancer risk is higher (22.9%)[31b,31c].

Thus, the heightened risk for cancer amongst adults with hypertension/higher BP occurs across different cancer cell types and anatomic locations; however, because some cancers are more and less common in hypertensives, their overall cancer risk may not always be elevated.

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al., Obesity, hypertension, and the risk of kidney cancer in men, N. Engl. J. Med. 2000;343:1305-1311.

[28] Christakoudi S et al., Blood pressure and risk of cancer in the European Prospective Investigation into Cancer and Nutrition, Int. J. Cancer 2020;146(10):2680-2693.

[29] *Id.*

[30] Lindgren AM et al., Cancer pattern among hypertensive patients in North Karelia, Finland J. Hum. Hypertens, 2005;19(5):373-379.

[31] *Id.*

[31b] Kasmari AJ, et al., Independent of Cirrhosis, Hepatocellular Carcinoma Risk Is Increased with Diabetes and Metabolic Syndrome. Am J Med. 2017;130(6):746.e1-746.e7.

[31c] Seretis A et al., Association between blood pressure and risk of cancer development: a systematic review and meta-analysis of observational studies. Sci Rep. 2019;9(1):8565. Published 2019 Jun 12.

The explanations of the hypertension and cancer epidemiological association have been multiple, though it is unclear which one is most explanatory. First, adult patients with hypertension also have co-morbidities, such as diabetes[32] and obesity, both of which are associated with heightened cancer risk. In 104,343 Taiwanese adults with diabetes followed between 1998 – 2009, diabetes mellitus was an independent risk factor, along with hypertension, for liver cancer.[33] Additionally, hepatitis C infection affects ~1% of the global population and is the major risk factor for hepatocellular carcinoma; the global incidence of new hepatitis C cases was 23.7 cases per 100,000 population in 2015 with approximately 10 – 20% developing cirrhosis or hepatocellular carcinoma.[34] Second, hypertension and cancer share common risk factors, such as alcohol intake, diet and physical inactivity; low physical activity, for example, is a risk factor for both kidney[35] and bladder cancer[36], while habitually high dietary salt intake has been linked to gastric cancer risk[37]. Third, certain antihypertensive drugs have been linked to augmented cancer risk—notably, calcium antagonists have been linked with prostate cancer,[38] and multiple antihypertensive drug classes including ACE inhibitors, ARBs, calcium antagonists,

[32] Giovannucci E et al., Diabetes and cancer: A consensus report, Diabetes Care 2010;33:1674-1685.
[33] Kasmari AJ et al., Independent of Cirrhosis, Hepatocellular Carcinoma Risk Is Increased with Diabetes and Metabolic Syndrome, Am J Med. 2017;130(6):746.e1-746.e7.
[34] Spearman CW et al., Hepatitis C, Lancet 2019; 394:1451 – 1466.
[35] Behrens G et al., The association between physical activity and renal cancer: systematic review and meta-analysis, Br. J. Cancer 2013;108(4):798-811.
[36] Keimling M et al., The association between physical activity and bladder cancer: systematic review and meta-analysis, Br. J. Cancer 2014;110(7):1862-1870.
[37] D'Elia L et al., Habitual salt intake and risk of gastric cancer: a meta-analysis of prospective studies, Clin. Nutr. 2012;31(4):489-498.
[38] Cao L et al., Antihypertensive drugs use and the risk of prostate cancer: a meta-analysis of 21 observational studies, BMC Urology 2018;18:17.

and diuretics have been linked to kidney cancer and/or bladder cancer[39]. However, the detection of elevated cancer risk amongst un-medicated hypertensives means that antihypertensive drugs, per se, do not explain entirely the linkage of certain cancers with hypertension. Fourth, drug exposures to agents used to treat hypertension co-morbidities have been linked to cancer—for example, the drug metformin (reduced risk), as well as insulin therapy (increased risk), used to treat diabetes have been linked to liver cancer, as have various cholesterol-lowering medications (reduced risk).[40] Fifth, it is possible, though not widely believed plausible, that hypertension might directly increase the risk of malignant cell transformation.[41] Thus, there are a multiplicity of factors that influence the risk of cancer in patients with hypertension.

VI. Valsartan for Effective Hypertension Treatment

As discussed above, valsartan is one of many ARBs that is commonly used for hypertension treatment. Valsartan is available in four different dosage strengths: 40 mg, 80 mg, 160 mg, and 320 mg. In my experience, valsartan is a safe medication that is effective in treating and controlling hypertension. I personally have prescribed valsartan to many patients, and those patients have had successful outcomes, including lower blood pressure and reduced hypertension symptoms, while taking valsartan.

[39] Xie Y et al., Antihypertensive medications are associated with the risk of kidney and bladder cancer: a systematic review and meta-analysis, Aging 2020;12(2):1545-1562.
[40] Kasmari AJ et al., Independent of Cirrhosis, Hepatocellular Carcinoma Risk Is Increased with Diabetes and Metabolic Syndrome, Am. J. Med. 2017;130(6):746.e1-746.e7.
[41] Giordano G et al., Postmenopausal status, hypertension and obesity as risk factors for malignant transformation in endometrial polyps. Maturitas. 2007;56(2):190-197.

VII. Valsartan Recall and Impact on Hypertension Patients

In July 2018, manufacturers of medications containing the active pharmaceutical ingredient valsartan began initiating voluntary recalls of their products after certain lots were found to contain trace amounts of the unexpected impurity NDMA.[42] In November 2018, another unexpected impurity, NDEA, was found in trace amounts of valsartan products, and as a result, additional voluntary recalls were initiated by the manufacturers of the valsartan products at issue. Nitrosamines, such as NDMA and NDEA, are commonly found in everyday products and sources; for example, as the FDA has recognized, nitrosamines are present "in water and foods, including cured and grilled meats, dairy products and vegetables."[43] The FDA has thus estimated that the additional risk posed by ingesting valsartan containing NDMA or NDEA is extremely low—specifically, according to FDA, "if 8,000 people took the highest valsartan dose (320 mg) containing N-Nitrosodimethylamine (NDMA) from the recalled batches daily for four years [amount of time the FDA believed NDMA-containing valsartan was on the US market before recall], there may be one additional case of cancer over the lifetimes of those 8,000 people."[44] And, as the FDA has recognized, that estimate likely overstates the actual risk, as the majority of patients taking valsartan are not prescribed the maximum dose of 320 mg. Moreover,

[42] Center for Drug Evaluation and Research, ARB Recalls: Valsartan, Losartan and Irbesartan. U.S. Food and Drug Administration, *available at* https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan (last visited July 6, 2021).

[43] FDA, *Information About Nitrosamine Impurities in Medications*, https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications (last visited July 5, 2021).

[44] *See* FDA, *Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications*, https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications (Aug. 28, 2019).

prescribed antihypertensive medications are never actually started/taken by the patient in many cases (~20%),[45] and within one year nearly 50% of patients have discontinued their prescribed antihypertensive medication,[46] which suggests the patient impact of NDMA/NDEA found in valsartan is even less than forecasted by FDA.

In initiating their voluntary recalls of valsartan, manufacturers and the FDA warned physicians and patients not to discontinue valsartan use. As the FDA correctly explained: "[T]he risks of stopping taking an ARB product for treating high blood pressure and heart failure greatly outweighs the potential risk of exposure to trace amounts of nitrosamines."[47] In my experience, abruptly stopping antihypertensive medications such as valsartan can have a serious adverse result for the patient, including loss of blood pressure control, or in extreme situations, stroke or new onset or worsening heart failure. In my opinion, patients stopping their antihypertensive drug is a safety risk that outweighs any miniscule risk caused by further exposure to NDMA and/or NDEA until a readily available alternative ARB can be substituted or prescribed.

When the valsartan recalls occurred, physicians, including myself, had to find alternative treatment options for patients previously prescribed valsartan. In my personal experience, I did not witness any patients have an adverse effect as a result of the NDMA/NDEA impurities found in valsartan.

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[45] Fischer MA et al., Trouble getting started: predictors of primary medication nonadherence, Am. J. Med. 2011;124(11):1081.e9-1081.e1.081E22.
[46] Vrijens B et al., Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories. BMJ. 2008;336(7653):1114-1117.
[47] *See* FDA, *Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications*, https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications (Aug. 28, 2019).

VIII. Medical and Scientific Literature Does Not Support a Causal Relationship Between Trace Amounts of NDMA/NDEA in Valsartan and Cancer Development.

Based on my medical education, training, and experience, and my review of the medical and scientific literature and materials in this case, it is my opinion that there is insufficient scientific evidence to establish that trace amounts of NDMA or NDEA in valsartan caused the types of cancers Plaintiffs allege in this litigation. Plaintiffs' cancer disclosure lists various types of cancer: bladder, blood, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, pharyngeal, prostate, and uterine cancer.[48] However, in my education, training, and experience, patients prescribed valsartan do not develop those cancers at a higher rate than patients prescribed other antihypertensive medications. Moreover, I have conducted a thorough review of the relevant literature on valsartan use and cancer incidence, including the literature cited by Plaintiffs' experts in this litigation, and the literature simply does not support a causal association between exposure to trace amounts of nitrosamines in valsartan and cancer development. I will discuss my assessment of the key literature on this subject in turn:

Animal Studies Versus Human Exposure to NDMA/NDEA:

There are no direct human exposure studies for NDMA/NDEA in the published literature because it would be unethical to purposefully expose humans to a potential carcinogen. Thus, the only direct NDMA/NDEA exposure studies available are animal studies. However, there are vastly different exposures to NDMA/NDEA (per kg of body weight) between animals in the available studies and humans taking

[48] *See* Dkt. No. 706.

NDMA/NDEA-containing valsartan. This massively different exposure is demonstrated by the following exercise:

The European Medicines Agency estimated that a person taking NDMA-containing valsartan at the highest dose (320 mg) daily for seven years, based on the average level of impurity detected in the active substance from Zhejiang Huahai Pharmaceuticals (60 parts per million), that there would be one extra case of cancer per 5000 patients.[49] Over the course of 4 years (more likely time of ingestion of NDMA-containing valsartan), assuming that not one daily dose of valsartan was missed and that the patient remained on this maximum dosage of valsartan the entire time (consuming recalled valsartan with NDMA actually above the upper range of NDMA found in the recalled lots), the cumulative exposure would be 3,518,600 ng of NDMA and 504,200 ng of NDEA. For a 70 kg adult, the cumulative exposure would therefore be 50,266 ng/kg of NDMA and 7203 ng/kg of NDEA. In reality, actual exposures of individual patients are likely much lower due to differences in dosage of valsartan, missed doses, not remaining on valsartan for a full four years, and not all batches of valsartan having the same levels of NDMA or NDEA. Contrast these exposures to the much larger shorter-term exposures in animal models. A case in point is the study by Anderson and colleagues who administered a dose of 5 mg/kg of NDMA to male mice over 12 – 72 weeks, which caused lung tumors, with several-fold greater efficiency when ethanol was co-administered[50]; this dose, however, is

[49] European Medicines Agency, Update on review of recalled valsartan medicines: Preliminary assessment possible risk to patients, *available at* https://www.ema.europa.eu/en/news/update-review-recalled-valsartan-medicines-preliminary-assessment-possible-risk-patients (Aug. 2, 2018).
[50] Anderson LM et al., Characterization of ethanol's enhancement of tumorigenesis by N-nitrosodimethylamine in mice, Carcinogenesis 1992;13(11):2017-2111.

5,000,000 ng/kg of body weight and is ~100-fold greater of a dose of NDMA per kg body weight than the FDA estimated a human would have received over 4 years taking the maximal approved daily dose of valsartan (320 mg).

The remaining available animal studies on NDMA/NDEA exposure and cancer, which are listed on my materials reviewed list attached as Exhibit B, contain this and/or other flaws or factors that make direct extrapolation to humans highly problematic. For example, in addition to the vast differences in dose amounts mentioned above, animals in many of these studies were exposed to NDMA/NDEA through injection or other non-oral routes of administration, which are distinguishable from the oral ingestion used in the case of valsartan and directly impact metabolic processes. Thus, the direct extrapolation to humans of the tumorigenesis observed in animal studies, as Plaintiffs' experts have attempted to do in this litigation, is highly problematic.

Occupational Studies:

Plaintiffs' experts in this litigation also rely upon several studies of occupational exposure to nitrosamines that are distinguishable from potential exposure to NDMA/NDEA in valsartan, and therefore are not relevant to the issue of general causation.

In an article by Hidajat M et al., lifetime exposure to rubber dust, rubber fumes and N-nitrosamine with cancer mortality in a cohort of British rubber workers (N = 36,441 men) aged 35 and older, over 49 years (1967 – 2015) follow-up, was

reported.[51] Median age of the cohort was 50.1 years while the median age at death from cancers was 60 – 75 years. Cumulative lifetime exposure was reported for NDMA with cancer using a competing risk survival analysis. NDMA cumulative lifetime exposure was linked to a doubling of the risk for all cancers and cancers of the bladder, stomach, leukemia, multiple myeloma, prostate and liver. Similarly, lifetime cumulative exposure to rubber dust and rubber fumes were associated with increased mortality from all cancers and specifically cancers of the bladder, lung, stomach, leukemia, multiple myeloma, non-Hodgkins lymphoma, esopahagus, prostate, pancreas and liver.

This data in Hidajat M et al. shows that in nearly half a century of follow-up in occupationally exposed rubber workers the increased risk of cancer with NDMA exposure while simultaneously exposed to other carcinogens, rubber fumes and rubber dust, both of which exposed the workers to NDMA via inhalation, were also linked to increased cancer risk. There is minimal relevance of the findings of this study to the question of whether NDMA exposure via oral ingestion over a relatively short period of a few years caused excess cancer risk.

In McElvenny DM et al., mortality patterns in a British rubber workers cohort in men 35 years of age and older followed over 49 years (1967 – 2015) were compared to the male population of England and Wales using standardized mortality ratios.[52] SMRs > 1 mean there is higher than expected mortality in the rubber worker

[51] Hidajat M, McElvenny DM, Ritchie P, et al., Lifetime exposure to rubber dusts, fumes and N-nitrosamines and cancer mortality in a cohort of British rubber workers with 49 years follow-up, Occup. Environ. Med. 76(4):250-258 (2019).
[52] McElvenny DM, Mueller W, Ritchie P, et al., British rubber and cable industry cohort: 49-year mortality follow-up, Occup. Environ. Med. 75(12):848-855 (2018).

cohort while < 1 means there is lower than expected mortality in this same cohort. SMRs were significantly elevated, especially for cancers of the stomach (1.26), lung (1.25), and bladder (1.16); deaths from leukemia, non-Hodgkins lymphoma, and multiple myeloma, however, were not higher. Bladder cancer risk was higher only in workers exposed to 1-naphthylamine and 2-naphthylamine, both antioxidants. Overall there were 9227 cancer deaths; the SMR for all malignancies was 1.13. This SMR corresponds to 1062 excess cancer deaths over 49 years in the rubber worker cohort, or ~ 22 excess cancer deaths per year in men exposed to multiple potential carcinogens via multiple routes of exposure.

The McElvenny DM et al. study is not relevant to the question of whether short-term exposure to NDMA-containing valsartan tablets caused detectable excess cancer risk in exposed humans who orally ingested this medication. The inhalation route of exposure to rubber dust and fumes, the nearly half century of follow-up and the inability to isolate the impact of NDMA on study outcomes are all problematic.

Another occupational study relied upon by Plaintiffs' experts is Straif K. et al., which involved a cohort of 8933 rubber workers hired after January 1, 1950 who were still active or retired in January 1981 and were employed for at least one year at one of five study factories, and were followed for mortality from January 1, 1981 through December 31, 1991.[53] Work histories and cost-center codes were used to construct semi-quantitative exposures to nitrosamines (low, medium and high). Rate ratios (low = reference) for the medium and high exposure categories were constructed to

[53] Straif K, Weiland SK, Bungers M, et al., Exposure to high concentrations of nitrosamines and cancer mortality among a cohort of rubber workers, Occup. Environ. Med. 57(3):180-7 (2000).

estimate the risk of cancer. Nitrosamine exposure was significantly associated with an increased mortality from cancer of the esophagus, oral cavity and pharynx. No association was found between exposure to nitrosamines and cancer of the stomach or lung. There was a suggestion, though not statistically significant, of increasing mortality from cancer of the prostate and brain.

The reference group in the Straif K. et al. analysis was not a minimally to un-exposed group but rather had low estimated exposure to nitrosamines. Also, this group was a survivor cohort as they had to be hired after January 1, 1950 but also had to survive to January 1981 to be included in the reported follow-up. Again, there was no control of exposure to other potential carcinogens making it impossible to isolate the effect of any one exposure on the reported study outcomes. Thus, the reported findings in this study are of no consequence in understanding whether short-term exposure to NDMA-containing valsartan caused excess cancers as claimed.

Valsartan Studies:

Gomm et al. conducted a cohort study involving data collected from a German health insurance company involving patients who filled prescriptions for valsartan from 2012 to 2017.[54] Of the total 780,871 patients 40 years and older who had filled a prescription for valsartan in the specified time period, the authors found there was no association between exposure to valsartan containing NDMA and the overall risk of cancer nor was there a dose-response relationship between NDMA and cancer risk; also, there was no difference in cancer risk amongst those exposed to valsartan

[54] Gomm, W. et al., N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer – A Longitudinal Cohort Study Based on German Health Insurance Data, at 357 (2021).

containing NDMA relative to those who filled prescriptions for valsartan that did not contain NDMA. However, the authors determined that "[a] statistically significant association was found . . . between exposure to NDMA-contaminated valsartan and hepatic cancer."[55] The age- and sex-adjusted risk of liver cancer was increased by ~4 cases/100,000 going from 34.6 cases to 39.1 cases/100,000. This study was a non-randomized retrospective, observational study of health insurance data. The study, as the authors admit, could not control for the many potential confounding factors (leads to residual confounding) that could have led to the erroneous statistical linkage of NDMA exposure to liver cancer in these patients.[56] Moreover, as the authors acknowledge, the study "can only state the existence of a statistical association[;] [c]ausality cannot be inferred."[57]

Another article by Al-Kindi et al. studied trends in adverse event reporting to FDA in the wake of the valsartan recalls.[58] The authors studied adverse events submitted through the FAERS database between January 1, 2017, and December 31, 2018, and compared the number of events as well as the percentage of neoplasm events reported by drug type (valsartan versus other ARBs). Authors found that following the 2018 recall, the number of adverse events increased more significantly for valsartan than for other ARBs, and the reporting odds ratio for neoplasm adverse events for valsartan increased from 1.7 pre-recall to 7.1 post-recall. The authors

[55] *Id.*
[56] *Id.* at 359 ("Although we adjusted our analysis by including numerous potential influencing factors, some risk factors for cancer, such as smoking habits, nutritional habits, and genetic predisposition, are not available in routine health insurance data and, therefore, could not be integrated into the analysis.").
[57] *Id.* at 360.
[58] Al-Kindi, S. et al., Abrupt Increase in Reporting of Neoplasms Associated with Valsartan After Medication Recall, Circ. Cardiovascular Qual. Outcomes, at 1 (2019).

specifically observed "an abrupt and biologically implausible rise in valsartan-associated neoplasms in the third quarter of 2018, after a drug recall that attracted extensive national media coverage."[59] Further underscoring the impact of the recall—and not a true causal association between valsartan use and cancer—the authors noted that "the duration of this effect was transient, as most cancer [adverse events] were reported early after the recall and decreased over time, remaining above baseline."[60] As the authors concluded: "[T]his observed phenomenon was likely associated with public alarm and fueled mainly by consumer and lay reporting. Government-sponsored strategies for patient and provider education are urgently needed to avoid premature discontinuation, legal disputes, and inaccurate drug-[adverse event] associations associated with valsartan and more broadly, with other recalled medical therapies."[61]

Finally, an article by Pottegard et al. presents the results of a Danish cohort study involving 5,150 patients with no history of cancer who used valsartan between January 1, 2012, and June 30, 2017.[62] The study followed patients for a median time of 4.6 years, and compared cancer outcomes in patients who used valsartan products potentially containing the unexpected NDMA impurity and patients treated with valsartan products that were not identified as being from one of the affected lots. The authors reported 198 cancer cases among patients taking valsartan potentially containing NDMA, and 104 cancer cases among patients not exposed to NDMA. The authors thus concluded that they "did not see an increased short term overall risk of

[59] *Id.*
[60] *Id.* at 2.
[61] *Id.*
[62] Pottegard, A. et al., Use of N-Nitrosodimethylamine (NDMA) Contaminated Valsartan Products and Risk of Cancer: Danish Nationwide Cohort Study, at 1 (2018) + Supplement.

cancer associated with the use of valsartan products potentially contaminated with N-nitrosodimethylamine (NDMA)."[63]

Thus, the available medical and scientific literature, including the animal studies on NDMA/NDEA exposure and occupational exposure studies, and publications examining the effect of NDMA/NDEA in valsartan, does not establish that trace amounts of NDMA or NDEA in valsartan cause an independent or increased risk of cancer.

IX. Shared Risk Factors Between Hypertension and Cancer Are More Likely to Have Contributed to Plaintiffs' Claimed Cancers Than Are Trace Amounts of NDMA or NDEA.

I have observed in my practice, having treated thousands of hypertension patients, several shared risk factors between hypertension and cancer, including smoking, alcohol, unhealthy diet, and lack of physical activity. Individuals with hypertension can be at a heightened risk of developing cancer because of the underlying risk factors often associated with both hypertension and cancer, medications used to treat hypertension, as well as medications used to treat common comorbidities such as diabetes, and perhaps due to hypertension itself. In terms of causality, these shared risk factors and exposures are significant and explain the putative association or correlation between NDMA/NDEA exposure in valsartan and cancer.

I do not believe it possible for an oncologist or other medical or scientific professional to say to a reasonable degree of medical or scientific certainty that the levels of NDMA or NDEA in therapeutic doses of valsartan between July 2012 and July

[63] *Id.* at 4.

2018 caused the cancers claimed by Plaintiffs,[64] or that valsartan increased the risk of the specific types of cancers alleged. There is no human clinical data showing that short-term exposure to valsartan potentially containing NDMA or NDEA was even associated with, much less caused, cancer in those exposed, as opposed to typically lifelong risk factors for both hypertension and cancer, such as smoking, alcohol intake, and lack of physical activity.

Nor do I believe it is possible for an oncologist or other medical or scientific professional to say to a reasonable degree of medical or scientific certainty that any Plaintiff would not have developed cancer if they had not taken valsartan medication.

X. Conclusion

My following opinions are based on grounds in scientifically and medically valid reasoning and methodology. Based on my medical education, training, and experience and my review of the medical and scientific literature and materials provided in this case, and to a reasonable degree of medical and scientific certainty, it is my opinion that:

1. The trace amounts of NDMA/NDEA found in valsartan do not independently cause, or increase the risk of, the types of cancers alleged by Plaintiffs;

2. No medical professional could credibly claim that Plaintiffs' cancers are caused by their use of valsartan, given the lack of corroboration of independent or

[64] Plaintiffs' cancer disclosure lists bladder, blood, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, pharyngeal, prostate and uterine cancer. *See* Dkt. No. 706.

augmented cancer risk in large human cohort studies using the same levels of NDMA/NDEA and conducted over a period of time similar to Plaintiffs' exposure;

3. No medical professional could credibly claim that any Plaintiff would not have developed cancer had they not taken valsartan; and

4. Hypertensive patients carry a higher incidence of cancer risk than the general population, and typically have comorbidities that are risk factors for various cancers—these factors are far more likely to cause cancer in a hypertension patient than short-term exposure to trace amounts of NDMA/NDEA in valsartan.

These are my opinions concerning the issue of general causation in this litigation. I have a sufficient factual basis and good grounds for my conclusions, and they are made to a reasonable degree of medical and scientific, and are based on my education, training, and experience.

I reserve the right to modify this report as additional information is provided to me, including but not limited to additional discovery and the depositions of Plaintiffs' experts which are ongoing.

I may use at trial any exhibits as a summary or in support of all of my opinions including: (1) any of the materials, or excerpts identified in this report and attachments, including the materials considered list; (2) excerpts from scientific articles or learned treatises; (3) demonstrative models; (4) exhibits used by Plaintiffs' experts, or other witnesses; and (5) any exhibit used in or identified at any deposition taken in this litigation. To the extent further information is disclosed or published, I will be happy to review it for consideration in modifying any portion of these opinions.

Dated: August 2, 2021

John Flack, M.D.

FLACK

EXHIBIT A

Date of preparation: June 28, 2021

John M. **Flack**, MD, MPH, FAHA, MACP

Date: _____

CURRICULUM VITAE

JOHN M. FLACK, MD, MPH, FAHA, MACP, FASH

Clinic Address SIU School of Medicine
Department of Internal Medicine
751 N. Rutledge St.; Room 1100
Springfield, IL 62794-9648

Office: SIU School of Medicine
Department of Internal Medicine
701 N. First St., Ste. D442
PO Box 19636
Springfield, IL 62794-9636

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Springfield, IL 62711

Telephone: (217) 545-2596 (O)
(217) 545-8156 (F)

E-mail: jflack47@siumed.edu (O)
Jmarkguppy@aol.com (H)

PERSONAL DATA:

Date of Birth: January 23, 1957, Hill AFB, Davis County, UT
Marital Status: Married, Jennifer Schoats Flack, J.D.
Number of Children: Five daughters

EDUCATION:

8/88-6/90 M.P.H., (Epidemiology) University of Minnesota School of Public Health, Minneapolis, MN

8/88-6/90 Postdoctoral Research Fellow, (Cardiovascular Epidemiology) National Heart Lung and Blood Institute (NHLBI), Division of Epidemiology, University of Minnesota School of Public Health Minneapolis, MN

8/86-6/88 M.P.H., Program University of Oklahoma School of Public Health, Oklahoma City, OK

07-08,1987 Fellow, 13th U.S. Ten-day Seminar on the Epidemiology and Prevention of Cardiovascular Diseases, Sponsored by the American Heart Association, Lake Tahoe, CA

7/85-6/86 Chief Medical Resident, Department of Medicine, University of Oklahoma Health Sciences, Oklahoma City, OK

7/82-6/85	Internship/Residency, University of Oklahoma Health Sciences Center, Oklahoma Memorial Hospital, Oklahoma City, OK
7/78-6/82	M. D., University of Oklahoma School of Medicine, Oklahoma City, OK.
8/74-6/78	B.S., Chemistry (Math Minor), Langston University, Langston, OK

RESEARCH INTERESTS:

1) Clinical trial design, implementation, and monitoring

2) Utilization of ambulatory clinical databases to make minimally-biased estimates of the effect of hypertension treatment strategies not easily studied in RCTs

3) The vascular phenotype of resistant hypertension; characterization of salt-responsive biomarkers in resistant hypertension

4) Developing and validating clinical and vascular risk prediction markers/algorithms for prediction of new-onset resistant hypertension

FACULTY APPOINTMENTS:

2019	Sergio Rabinovich Endowed Chair of Internal Medicine
6/2016-present	Chief, Hypertension Section
5/2015-present	Professor of Medicine and Chair, Department of Internal Medicine Southern Illinois University School of Medicine, Springfield, Illinois
6/2014-5/2015	Professor of Medicine and Physiology Wayne State University School of Medicine, Detroit, Michigan
3/2008-5/2014	Chairman Department of Internal Medicine Wayne State University School of Medicine
3/2005-3/2008	Interim Chairman Department of Internal Medicine Wayne State University School of Medicine
4/2000-2/2005	Associate Chairman for Academic Affairs and Chief Quality Officer Department of Internal Medicine, Wayne State University School of Medicine
1/1999-3/2000	Associate Chairman for Clinical Research and Urban Health Outcomes Department of Internal Medicine, Wayne State University School of Medicine
1/1999-6/2003	Graduate Faculty Appointment, Professor, Department of Community Medicine Wayne State University School of Medicine
7/1997-12/1998	Associate Chairman, Department of Internal Medicine Wayne State University School of Medicine
7/1997-6/2003	Professor, Departments of Internal Medicine and Community Medicine

	Wayne State University School of Medicine
7/1994-6/1997	Associate Professor of Surgery, Medicine and Public Health Sciences Bowman Gray School of Medicine, Winston Salem, North Carolina
6/1994-6/1996	Associate Professor, Division of General and Preventive Medicine, University of Minnesota School of Medicine, Minneapolis, Minnesota
9/1992-5/1994	Assistant Professor, Division of General and Preventive Medicine University of Minnesota School of Medicine
7/1990-8/1992	Assistant Professor, School of Public Health, Division of Epidemiology University of Minnesota
7/1986-7/1988	Instructor of Medicine University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma

HOSPITAL OR OTHER PROFESSIONAL APPOINTMENTS:

2019-present	Member, Continuous Quality Improvement Group (CQI), LCME Faculty Subcommittee
2019	Member, SIU Misconduct in Science Committee
2018	Mastership (MACP) American College of Physicians
2018	Member, American College of Physicians (ACP) Board of Regents
2018	President, American Hypertension Specialist Certification Program (AHSCP)
2014-2018	Vice President, American Hypertension Specialist Certification Program (AHSCP)
2017	Member, SIU Healthcare Board of Directors
2016	Chair, SIU School of Medicine Search Committee for Associate Dean of Research and Faculty Affairs
2013-2014	Chair, Nominating & Governance Committee, Wayne State University Physician Group
2012-2014	Board Member, Detroit Medical Center - PHO
2010-2015	Member, Advisory Board, Cardiovascular Research Institute (CVRI), Wayne State University
2009-2014	Secretary, Wayne State University Physician Group
2008-2015	Consultant, NIH R01 “Clinicians Concept of Genetics, Race and Ethnicity in Managing Chronic Illness”, Principal Investigator, Linda Hunt, Ph.D., Michigan State University
2007-2009	Vice Chair, Wayne State University Physicians Group

2007-2015	Member, Executive Committee of Wayne State University Physicians Group
2007	Wayne State University President Search Committee, member
2006-2014	Chief, Division of Translational Research and Clinical Epidemiology
2006	Vice-President for Research, Wayne State University Search Committee
2005-2015	Detroit Medical Center Cardiovascular and Thrombosis Pharmacy & Therapeutics Subcommittee
2005-2009	Consultant, Center for Disease Control-funded Center for Excellence for Training and Research
2005-2014	Specialist in Chief for Internal Medicine, Detroit Medical Center, Detroit, MI
2005- 2014	Medical Executive Committee, Detroit Medical Center, Detroit, MI
2005- 2014	Executive Management Team, Detroit Medical Center, Detroit, MI
2005- 2014	Harper University Hospital Leadership Team, Detroit Medical Center, Detroit, MI
2005	Cardiac & Vascular Institute Steering Committee, Detroit Medical Center, Detroit, MI
2004- 2015	Consultant, John D. Dingell Veterans Affairs Medical Center, Detroit, MI
1998-1999	Chief of Medicine, Detroit Medical Center, Central Region Hospitals, Detroit, MI
1998-1999	Acting Director, Division of General Medicine, Wayne State University School of Medicine
1998-2000	Vice President, Vencor Hospital, Detroit/Metro-Medical Staff, Detroit, MI
1997-2006	Director, Cardiovascular Epidemiology and Clinical Applications (CECA) Program, Department of Internal Medicine, Wayne State University School of Medicine
1994-1997	Associate Director and Medical Director, Hypertension Center, Bowman Gray School of Medicine
1992-1994	Director, Division of General and Preventive Medicine, University of Minnesota, Minneapolis, MN
1992	Co-Director, Division of General Medicine, University of Minnesota, Minneapolis, MN
1990-1991	Deputy Director, Institute of Preventive Cardiology and Medicine, Metropolitan Mount Sinai Medical Center, Phillips Campus, Minneapolis, MN
1990-1991	Medical Staff, Abbott-Northwestern Hospital, Minneapolis, MN

1989-1991	Medical/Emergency Room Staff, Metropolitan Mount Sinai Medical Center, Minneapolis, MN
1989-1991	Consultant, Quality Quest Inc., Minneapolis, MN
1989-1991	Consultant, United Healthcare Corp., Minneapolis, MN
1986-1988	Associate Director, Hypertension Center, University of Oklahoma Health Sciences Center, Oklahoma City, OK
1986-1988	Director, General Medicine Consult Service, University of Oklahoma Health Sciences Center
1977-1978	Research Chemist, Phillips Petroleum Company, Bartlesville, OK (summer)
1976	Analytical Chemist, AMOCO Production Company, Tulsa, OK (summer)

MEMBERSHIP SOCIETIES:

Sigma Pi Phi Fraternity
Alpha Omega Alpha (AOA) Medical Honor Society
American College of Physicians (fellow)
Association of Professors of Medicine
Association of Black Cardiologists (ABC)
Detroit Medical Academy
International Society on Hypertension in Blacks (ISHIB), Past President
National Medical Association (NMA)
Michigan Medical Society
American Heart Association (AHA)
- AHA Council for High Blood Pressure Research, member
  - Peer Review subcommittee, member
- AHA Council on Hypertension
  - Professional and Public Education & Publications Committee, member
- AHA Quality of Care and Outcomes Research, member
- AHA Functional Genomics and Translational Biology, member
- AHA Strategic Outcomes Subcommittee, member

American College of Cardiology (fellow)
American Medical Association
Frontiers International, Springfield IL Chapter

LICENSURE AND BOARD CERTIFICATION:

2015	Illinois
2012	Fellow, American Society of Hypertension (FASH)
1999-Present	Specialist in Clinical Hypertension, American Society of Hypertension (lifetime certification)
1997	Michigan (Active)
1994	North Carolina (Inactive)
1990	Basic Rescuer, American Heart Association
1990	Advanced Cardiac Life Support Provider, American Heart Association

1988	Minnesota (Inactive)
1985	Diplomate, American Board of Internal Medicine (lifetime certification)
1983	Diplomate, National Board of Medical Examiners
1982	Oklahoma (Inactive)

HONORS/AWARDS:

2019	Awarded "Internal Medicine/Hypertension Top Doctor 2019"
2018	Illinois ACP Downstate Chapter Laurate Award
2017-2018	"Best Doctors in America" St. Louis Magazine
2016	"Medical Innovator" Award, from Sangamon County (IL) Medical Society
2014	Top Doctor
2014	Detroit Super Doctors 2014 from Super Doctors.com
2013	'Top Doctor' from Who's Who Global Directory
2012	"Academic Physician of the Year" from Oklahoma University School of Medicine
2010	Hour Magazine Top Doc
2009	Michiganian of the Year as presented by The Detroit News
2009	Hour Magazine's Top Health Professional for Hypertension
2009	QFORMA's Most Influential Doctor in Hypertension, USA Today
2008	Fellow of the American College of Physicians (ACP)
2008	MPRO Pillar Award of Excellence
2007-2008	Selected as one of Detroit's Top Docs
2007	American Heart Association's F. Dewey Dodrill Award for Excellence
2005	*Crain's Detroit Business* Health Care Hero Award for Outstanding Physician Achievement
2005	Awarded Pillar Award of Excellence for Reducing Health Disparities, Michigan Peer Review Organization
2005-2006	Selected as one of the "Best Doctors in America"
2004	Who's Who Among Executives and Professional in Healthcare
2004	Distinguished "Alumnus" Award, Langston University-outstanding accomplishment in the field of medicine and serving as speaker for honors convocation
2004	Distinguished "Alfred Deutsch" Award Wayne State University-Dept of OBGYN
2003-2004	Selected as one of the "Best Doctors in America"
2003	Distinguished Service Award of the National Kidney Foundation, Inc.
2003	Attending of the Month of March, Wayne State University -Dept of Med Harper University Hospital
2002-2003	Selected as one of the "Best Doctors in America"
2001	Fellow of the American Heart Association (F.A.H.A.)
2001	Department of Internal Medicine Wayne State University College Teaching Award
2001	Life-term Member of The National Registry of Who's Who. Published 2002 ed.
1998-1999	Selected as one of the "Best Doctors in America," Woodward/White, Inc.
1998	Dr. Daniel D. Savage Memorial Scientific Award, Association of Black Cardiologists
1995	Pee Dee Newspaper Group, Positive Image Award
1995	Certificate of Appreciation for participation in the 11th Annual Martin Luther King Day Program, The University of Oklahoma Health Sciences Center
1994	Selected as Faculty for Bush Faculty Development Program in Excellence and Diversity in Teaching, University of Minnesota-Twin Cities
1993	Distinguished Research Award, International Society on Hypertension in Blacks
1993	Distinguished Alumni Citation of the Year, National Association for Equal Opportunity in Higher Education
1993	Gordon L. Starr Award Recipient, University of Minnesota
1992	Personalities of America

1992	Men of Achievement
1991	Who's Who Among Rising Young Americans Award
1988-1990	Higher Ability Minority Scholarship, University of Minnesota School of Public Health
1988	Special Recognition Award, University of Oklahoma Health Sciences Center, Student National Medical Association
1988	Black Student Services Special Recognition Award, University of Oklahoma Health Sciences Center
1985	Award of Academic Excellence, VA Medical Center, Afro-American Program
1982	Association of Black Personnel and Black People's Union, Outstanding Black Student Award, University of Oklahoma

AD HOC:

2018	Member Writing Committee, American Heart Association Scientific Statement on Resistant Hypertension
2017	NIH Invited Participant in the Training the Next Generation of Implementation Researcher for Health Equity, August 30-31
2016	Reviewer, National Institutes of Health, Fellowships Review Meeting
2015	American Heart Association Cardiorenal Clinical Peer Review Study Group
2015	Reviewer, "Support for the National Institute of Environmental Health Sciences (NIEHS) Clinical Research Program" (8/20-21/2015)
2015	Advisory Panelist, Emergency Medicine Perspective of Hypertension Management Advisory Panel, the Medicines Company (6/11/2015)
2014	Invited Participant, NHLBI Health Inequities Think Tank Meeting (9/2014)
2013	Invited Participant, Duke Resistant Hypertension Think Tank Meeting (8/2013)
2012-present	Director-at-Large, American Society of Hypertension Specialist Program
2013-14	Member, Program Committee, Council on High Blood Pressure Research
2011	Member, Fall Conference Committee, Council on High Blood Pressure Research (HBPR)
2011	Editorial Board member, Journal of Cardiorenal Medicine
2011	Chair, Ophthalmology Chair Search Committee, Wayne State University School of Medicine
2008	Member, Data Safety and Monitoring Board of the "Mechanisms of Meditation in Hypertension in Blacks Trial" (NIH Funded), PI: Robert S. Schneider, MD.
2006	Reviewer, NCMHD Special Emphasis Panel
2005	Reviewer, NCMHD Centers of Excellence in Partnership for Community Outreach, Research on Health Disparities and Training (Project EXPORT – Establishing Exploratory Centers)
2005	Member, NIH (NIEHS) High Profile Review Clinical Research Support Services
2005	Chair, Hypertension Expert Working Group (NKF of Michigan)
2005	Member, Research Review Committee Department of Internal Medicine
2005	Member, Wayne State University Research Advisory Committee
2005	Member, Wayne State University Population Sciences Panel
2005	Member, Wayne State University Hematology Oncology Academic Search Committee
2005	Member, Tarka Specialty Consultants Steering Committee
2005	Chair, CUAAH Health Disparities Committee
2004	Member, DMC Medical Staff, Informal Investigation Committee
2004	Member, Council for the Advancement of Diabetes Research & Education (CADRE)
2004	Member, Preventive Cardiology Junior Faculty Awards Steering Committee (Pfizer, Inc.)
2004-2005	Member, Wayne County Delegate (Wayne County Med Society of Southeast MI)

2004	Reviewer, National Health and Medical Research Council (Australia)
2004	Member, National Kidney Disease Education Program Committee (NKDEP)
2004	Member, Wayne State University Hutzel Women's Hospital, Disciplinary Investigation Committee
2004	Member, NIH National Heart Lung and Blood Institute Sub-clinical Cardiovascular Disease Working Group
2003	Member, Metro Detroit Health Care Disparities Task Force (HFH)
2003	Reviewer, National Institute of Diabetes & Digestive & Kidney Disease
2003-2005	Member, Wayne State University INPHASE (Institutes for Population Studies Health Assessment, Administration, Services and Economics)
2002	Member, Steering Committee, National Kidney Disease Ed Program
2002-2004	Member, Epidemiology and Clinical Trials Center (EpiCenter), ABC
2002	Member, Program Committee Clinical Nephrology Meeting 2002 (NKF)
2002	Member, Worldwide Advisory Board, Norvasc (amlodipine besylate)
2001	Member, American Heart Association's Scientific Committee Session 2001
2001-present	Consultant, Center for Disease Control (WISEWOMAN) Well-Integrated Screening and Evaluation for Women Across the Nation
2001	Member, Affiliated Internist's Data Analysis Committee
2001	Member, Affiliated Internist's Ambulatory Steering Committee
2001	Member, Affiliated Internist's Informatics Committee
2001	Member, Affiliated Internist's Quality Improvement/Chronic Disease Management Committee
2001	Member, National Institute of Dental and Craniofacial Research-Special Emphasis Panel
2001	Member, American Heart Association, Metropolitan Detroit Board of Directors
2001	Co-Chair, Upcoming "Sixth Congress on the Treatment of Cardiovascular Disease in African-Americans (Speaker and Session Moderator)
2001	Chair, (NIH) National Institutes of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis, Panel Review Group
2001	Member, Medical and Scientific Advisory Board (MSAB), National Kidney Foundation
2000	Member, Michigan Peer Review Organization (MPRO), Board of Directors
2000-2002	Member, Association of Professors of Medicine, Departmental Finance and Management Committee, Washington, DC
2000	Member, Mott Center, Advisory Committee, Wayne State University and DMC Detroit, Michigan
2000	Chairman, Cardiovascular Risk Factor: New Challenges, New Opportunities Part I: Angiotensin-II & Cardiovascular Risk, American College of Cardiology, (ACC) Anaheim, CA
1998	Member, PSO Contracting & Reimbursement Work Group and Managed Care Contract Review Committee, DMC, Detroit, Michigan
1998	Scientific Program Chairman, Third Annual Congress on the Treatment of Cardiovascular Diseases in African-Americans, Dallas, TX
1998	Reviewer, Abstracts for ACC 48th Annual Scientific Session, Dallas, TX
1998	Reviewer, K23 and K24 Grant Awards, NHLBI
1997	Reviewer in Reserve, Agency for Health Care Policy
1997	Reviewer, Abstracts for American College of Cardiology (ACC) 47th Annual Scientific Session, Bethesda, MD
1997	Chairman, Expert Panel on Optimal Target-Organ Protection and Survival in African-Americans, Orlando, FL
1997	Scientific Program Chairman, Second Annual Congress on the Treatment of Cardiovascular Diseases in African-Americans, Orlando, FL
1997	Reviewer, "Clinical Trials Unit", NIDDK, U01 DK54047-01

1996	Grant Reviewer, Agency for Health Care Policy Research, Office of Scientific Affairs, Rockville, MD
1994	Member of Writing Group, National High Blood Pressure Education Program Working Group on Hypertension and Renal Disease
1992	Reviewer, "The Biology of Kidney Disease and Hypertension in Blacks", RFA DK/ 92-11
1991	Member, Writing Group to Revise American Heart Association Recommendations for Human Blood Pressure Determination by Sphygmomanometers
1991	Reviewer, NIH Small Grants Program (R03)
1991	Behavioral Science, Epidemiology and Prevention Study, American Heart Association
1990	Reviewer, NHLBI Bogalusa Heart Study, New Orleans

STUDY SECTIONS:

2014-2018	Member, National Institute of Health NHLBI Institutional Training Mechanism Review Committee
2007-2010	Member, Environmental Health Sciences Review Committee of the National Institute of Environmental Health Sciences
2007-2011	Member, Psychosocial Risk and Disease Prevention Study Section, Office of Behavioral and Social Sciences Research/NIH
1999-2001	Steering Committee, OPERA Study (International), Bristol Meyers Squibb
1998-2002	Member, Agency for Health Care Policy Research (AHCPR), Health Care Quality and Effectiveness Research (HCQER) Study Section
1992-1996	Member, Research Centers in Minority Institutions (RCMI) Review Committee, National Institutes of Health

PROFESSIONAL SERVICE:

2021-present	Member, AHA Manuscript Oversight Committee
2020-present	Chair, AHA Hypertension Professional Education and Publication Committee
2019-2020	Vice Chair, AHA HTN Professional & Public Education & Publications Committee
2019-present	ACP Education and Development Committee
2019-present	ACP Diversity and Inclusion Subcommittee
2019-present	AHA Council on Hypertension Leadership Committee
2019-present	AHA HTN Trainee Advocacy Committee of the Council on Hypertension
2018-present	American College of Physicians Board of Regents
2017-2019	AHA Research Strategic Outcomes Subcommittee
2018	Member, Association of Black Cardiologist (ABC) Advisory Group
2018	Vice Chair, American Heart Association (AHA) Hypertension Professional Education Committee
2016	Chair, Search Committee for the Associate Dean, Research (SIU)
2016-present	Associate Editor, American Journal of Hypertension
2015-2017	Vice President, American Society of Hypertension (ASH) Specialist Board
2015	Member, American Heart Association (National) Research Committee Member, Peer Review Subcommittee
2014 – 2016	Member, Professional and Public Education and Publications Committee of the Hypertension (HYPE) Council
2009	Member, Karmanos Cancer Center Director Search Committee
2009	Inaugural Member, Cardiovascular Research Institute Advisory Board, Wayne State University
2008-2015	Member, Affiliation Partnership VA/DMC/Wayne State University

2008	Member, Longitude Health: Guided Health and Wellness, Professional Advisory Board Translation, University of North Carolina at Chapel Hill
2005	Chair, Morehouse School of Medicine, Clinical Research External Advisory Committee
2005	Member, National Kidney Foundation, Hypertension Expert Group
2005	Member, Association of Professors of Medicine (APM)
2005	Member, Association of Professors of Medicine (APM) Diversity Subcommittee
2005	Member, Michigan Peer Review Organization (MPRO)
2005	Member, Metro Detroit American Heart Association
2005	Member, High Blood Pressure Council of the American Heart Association
2004	Member, Wayne County Medical Society Southeastern Michigan, Nomination and Election Committee
2004	Member, American Society of Hypertension, Inc, Board of Directors, Midwest Regional Chapter
2004	Immediate Past President, International Society on Hypertension in Blacks (ISHIB)
2003	Member, Medical and Scientific Advisory Board, National Kidney Foundation of Michigan
2002	Member, University Physician Services, Board of Directors
2001-2003	President, International Society of Hypertension in Blacks (ISHIB)
2002	Member, Henderson Scholars Program-University of Oklahoma-Leadership Advisory Committee
2001	Member, Wayne County Medical Society, Membership Committee
2001-2003	Member, Medical and Scientific Advisory Board, National Kidney Foundation
2001	Honorary Member, Pathfinders, in Medicine Awards Committee
2001	Member, Wayne State University Advisory Committee, Liborio Tranchida, MD, Endowed Chair Campaign, Detroit, MI
2001-2002	Member, DMC Managed Care Contract Review Committee, Detroit, MI
2001	Member, DMC Hutzel Women's Hospital Stages of Life Program Team", Detroit.
2001-2003	Ex-Officio, Member of National Kidney Foundation, Medical and Scientific Advisory Committee
2000-present	Chair, Affiliated Internist Investment Committee, Detroit, MI
2000-2001	Board of Directors, Member, United Medical Management Co., Inc., Detroit, MI
1999-present	Chair, DMC Central Region Credentialing Committee
1998-2000	Reviewer, Harper Hospital Medical Staff, Department of Medicine, Seed Grants
2000	Abstracter Grader, Annual Scientific Session American College of Cardiology
1999	Abstract Grader, American College of Cardiology 49th Annual Scientific Session
1999	Member, Internal Review Committee for the Department of Emergency Medicine, Wayne State University School of Medicine (Chair of Administrative Review)
1998	Member, Senior Servicer Planning and Advisory Committee, Detroit Medical Center
1998	Member, PSO Contracting and Reimbursement Group, Detroit Medical Center
1998	Member, Pediatric Internal Review Committee, Wayne State University School of Medicine
1998-2003	Board Member, Consortium for Southeastern Hypertension Control (COSEHC), Wake Forest University Baptist Medical Center, Winston-Salem, NC
1996-present	Member, External Advisory Committee to the Interdisciplinary Cardiovascular Group of Morehouse School of Medicine
1996	(Special Government Employee), FDA, Center for Drug Evaluation and Research, Division of Metabolic and Endocrine Drug Products
1995-1998	Steering Committee, Breast Cancer Prevention Trial (BCPT)
1995-1997	Protocol Committee General Clinical Research Center (GCRC), Bowman Gray School of Medicine
1995-1997	Advisory Committee, General Clinical Research Center (GCRC), Bowman Gray School of Medicine
1995	National Kidney Foundation, Early Intervention & Prevention Task Force

1995-present	Board of Trustees, International Society on Hypertension in Blacks, Inc. (ISHIB)
1995-1997	Clinical Research Practices Committee (GCRC), Bowman Gray Medical School
1995	Chairman, Personnel Committee, International Society on Hypertension in Blacks, Inc. (ISHIB)
1995	Finance and Audit Committee, International Society on Hypertension in Blacks, Inc. (ISHIB)
1995-1996	Membership Committee, American Society of Hypertension
1995-1996	Chairman, Parke-Davis, Southeastern United States African American Initiative
1995-1997	Steering Committee, Breast Cancer Prevention Trial (BCPT)
1995-1997	Cardiovascular Committee, Breast Cancer Prevention Trial
1995	Bristol-Myers Squibb Diabetes Education Faculty
1993-1994	Long-Range Strategy Planning Committee, Department of Medicine, University of Minnesota
1993-1994	Chair, Primary Care Subcommittee of the Long-Range Strategy Planning Committee, Department of Medicine, University of Minnesota
1993-1994	Professional Services Committee, University of Minnesota
1993-1994	Advisory Council, HealthSpan Research
1993-1994	Managed Care Task Group, University of Minnesota Clinical Associates
1993-1994	Academic Affairs Faculty Working Group, University of Minnesota
1992-P resent	African-American Lipid and Cardiovascular Council (AALCC)
1992-1993	Agenda Planning Committee, American Heart Association
1991-1992	Who's Who Among Rising Young Americans
1991-1994	Board Member, American Heart Association, Minnesota Affiliate
1991-Present	The American Society of Hypertension
1990-1991	Subcommittee, Epidemiology MPH Admissions, University of Minnesota School of Public Health
1990-Present	Research Awards Committee, Division of Epidemiology, University of Minnesota School of Public Health
1988-2015	Faculty Advisor, Student National Medical Association, University of Oklahoma College of Medicine Chapter
1987-1988	Residency Advisory Committee, Department of Medicine, University of Oklahoma
1987-1988	Seed Grant Review Committee, University of Oklahoma College of Medicine
1986-1988	Quality Assurance Committee, Oklahoma Foundation for Peer Review
1986-1988	Medical Records Committee, Oklahoma Memorial Hospital
1986-1988	Medical College Admissions Board, University of Oklahoma College of Medicine
1986-1987	Advisory Committee, Industrial Cooperative Education, Douglas High School, Oklahoma City, OK
1982-1983	Long-Range Planning Committee, Oklahoma University Health Sciences Center
1981-1982	Medical College Admissions Board, Oklahoma University Health Sciences Center

EDITORIAL BOARDS:

2014-	Metabolic Syndrome and Drug Therapy
2014-	Journal of Endocrine Disorders
2014-	Journal of Clinical Nephrology and Research
2013-Present	Annals of Clinical & Experimental Hypertension
2013-Present	Journal of Endocrinology, Diabetes & Obesity
2013-Present	British Biotechnology Journal
2012-Present	Advances in Combination Treatments for Hypertension
2012-Present	Journal of Diabetes Research and Clinical Metabolism (JDRCM)
2011-Present	Clinical and Experimental Pharmacology and Physiology
2011-Present	Kidney and Blood Pressure Research

2011-Present	CardioRenal Medicine
2009-Present	International Journal of Hypertension
2009-Present	Hypertension
2008-Present	Integrated Blood Pressure Control
2007-Present	Therapeutic Advances in Cardiovascular Disease
2006-Present	Journal of Clinical Hypertension
2006-Present	Current Cardiovascular Risk Reports
2005-Present	Current Hypertension Reviews
2003-Present	Hypertension
2003-Present	Internal Medicine/Cardiology News
1993-1998	ABC Digest of Urban Cardiology
1992-1994	Issues in Hypertension and Atherosclerosis
1992-1995	Urban Health
1991-1998	Obesity and Health
1990-Present	Journal of Ethnicity and Disease

MANUSCRIPT REVIEWER:

Advanced Studies in Medicine (ASiM)
American Journal of Cardiovascular Drugs
American Journal of Alzheimer's Disease and other Dementias
American College of Cardiology (Abstract Grader)
American Journal of Epidemiology
American Journal of Hypertension
American Journal of Medicine
American Journal of Nephrology
American Journal of Physiology – Heart and Circulatory Physiology
Annals, Academy of Medicine, Singapore
Annals of Clinical and Experimental Hypertension
Archives of Internal Medicine
BMC Cardiovascular Disorders
British Biotechnology Journal
Cardiology & Therapy
CardioRenal Medicine
Circulation (Journal of the American Heart Association)
Clinical and Experimental Pharmacology and Physiology
Diabetes Care
Diabetes Metabolism Research and Reviews
Expert Opinion on Pharmacotherapy
Expert Review of Endocrinology & Metabolism
Future-Drugs Ltd
Heart Failure Reviews
Hypertension
Hypertension Research
Integrated Blood Pressure Control
International Journal of Clinical Practice
Journal of the American College of Cardiology (JACC)
Journal of the American Medical Association
Journal of the American Society of Hypertension (JASH)
Journal of the Cardiometabolic Syndrome
Journal of Clinical Hypertension
Journal of Ethnicity and Disease

Journal of Ethnicity and Health
Journal of Laboratory and Clinical Medicine
Journal of Neurological Sciences
Journal of General Internal Medicine
Journal of Behavioral Medicine
Journal of Human Hypertension
Journal of Experimental Medicine
Journal of American Geriatric Society
Journal of Vascular Medicine
Journal of the Renin Angiotensin Aldosterone System
Lipids in Health and Disease
Mayo Clinic Proceedings
Medical Care
Medicine
Nature Clinical Practice Cardiovascular Medicine
Nutrients Reviews Cardiology
Post Graduate Medicine
Preventive Medicine
Public Health Association
Redox Report
Therapeutic Advances in Cardiovascular Disease
West Indian Medical Journal
Women's Health in Primary Care

ASSOCIATE EDITOR

American Journal of Hypertension
CardioRenal Medicine (ended 2018)
International Journal of Hypertension (2014 - 2017)

COMMUNITY SERVICE:

2018	Member, Springfield Urban League Board of Directors
2018	Member, Frontiers International, Springfield Chapter
2016	Central Management Services Home Health webinar "One Giant Leap for Preventive Cardiovascular Care"
2015	Springfield (IL) Branch NAACP general meeting "Health Concerns for People of Color"
2013	New Detroit "Impacting Institutional Practices Health Disparities Work Group".
2008	Detroit Public Library - Black History Month "Changes That Will Make a Difference Today and Tomorrow: What the Current Research Demonstrates"
2005	Owen Elementary Head Start Program-March Parent Meeting "Preventing Hypertension, Heart Disease & Diabetes in our Children with Proper Nutrition"
2005	Center for Urban and African American Health (CUAAH) -Past Present & Future of African American Research
2004	Center for Urban and African American Health (CUAAH) -Annual Martha G. Scott Health Screening Fair
2004	Helping Educate African American and Latinos on research being conducted on health disparities "Cutting Edge Newsletter" ***(article written on CUAAH)***
2003-2015	Mentoring Program Wayne State University-School of Medicine
2003	Wayne County Community College "Combating Health Disparities" (lecture/panel)

2003	Wayne County Department of Health "Cardiovascular Drug Therapy Which Drug for Which Patient" (lecture/discussion)
2002	Wayne State University-CECA Program, "Health Screening Fair"
2001	Senator Raymond M. Murphy's African American Health Conference
2001	NIH National High School Students Summer Mentoring Research Program
2001	100 Black Men of Greater Detroit
1994	Hennepin County Medical Society, "Success By 6" Program
1994	Mentor Program at Willard Math, Science and Technology Elementary School

TEACHING:

2016 Southern IL University School of Medicine
Grand Rounds, "Is Vitamin D Deficiency an Important Therapeutic Target?"

2015 Southern IL University School of Medicine
Grand Rounds, "Demystifying the Enigma of Resistant Hypertension"

2007 Wayne State University
Presidential Health Disparities Conference
"Is Vitamin D an Important Cause of Obesity as Well as a Mediator of Obesity-Related Disease?"

Wayne State University
Summer Lecture Series
"Hypertension: Interns Part I"

Wayne State University
Neurology Grand Rounds
"Ruminations Regarding the Excess Cardiovascular-Renal Disease Burden in U.S. Blacks: Clues from Interlinked Deranged Physiological Pathways"

Wayne State University
Year II Clinical Medicine Course
"An Approach to Understanding Health Disparities"

Wayne State University
Year I Clinical Medicine Course
"Ethnic and Racial Disparities"

2005 Wayne State University
Department of Family Medicine/Clinical Medicine Lecture
"What is Race? What is Ethnicity?"

Wayne State University
Department of Family Medicine/Clinical Medicine Lecture
"An Approach to Understand Health Disparities"

Wayne State University
Resident Summer Lecture Series
"Hypertensive Urgencies, Emergencies, and BP Management During Acute Stroke"

Wayne State University Guest Lecturer, Community Medicine Students

"Cardiovascular Epidemiology: An Overview"

In-patient ward rounding, February (Detroit Receiving Hospital)

2004 Wayne State University
Dept of Medicine 2nd Asian American Conference
"What's New in Hypertension?"

DMC-Dept of Obstetrics & Gynecology (Sinai-Grace)
"Hypertension Therapeutics in Women: Special Issues"

Wayne State University-African American Student Society
"Unraveling Selected African American Health Disparities with a Multi-disciplinary Team"

Wayne State University Department of Medicine
Endocrinology Grand Rounds
"Why Does Sodium Raise BP in Obese Persons"
Synergy Medical Covenant Healthcare

Internal Medicine Grand Rounds
"Hypertension in Blacks"

Wayne State University
Medical Alumni Association Conference
"Obesity/Hypertension"

Wayne State University-Neurology Grand Rounds
"Management of BP in Acute Stroke, Hypertensive Emergencies and Urgencies"

Wayne State University
Emergency Medicine Grand Rounds
"Management/Disposition of New Onset & Uncontrolled Hypertension in the Emergency Department"

Wayne State University
Family Medicine Conference
"An Approach to Understand Health Disparities"

Grady Memorial Hospital-Grand Rounds
"The Pervasive Metabolic & Hemodynamic Consequences of Obesity: No Good News"

Wayne State University
Resident Summer Lecture Series
"Hypertension Update"

Wayne State University
Center for Urban and African American Health Lecture Series
"Obesity: The Pervasive Weapon of Mass Public Health Destruction"

Wayne State University Symposium
Michigan Consortium for Minority Health & Academic Development

"Racial & Ethnic Disparities: The looking glass into broader societal and health systems problems"

Wayne State University
American Medical Student Association Conference
"What are Healthcare Disparities"

Wayne State University-University Internal Medicine Specialists
Employee In-service lecture and discussion
"Hypertension: The Silent Killer"

Wayne State University
Department of Family Medicine/Clinical Medicine
"Ethnic & Racial Disparities in Health Status"

2003 Wayne State University
Grand Rounds "Clinical Patient Care"
Grand Rounds "Hypertension Update"

General Motors Occupational Health symposium "What's New in Hypertension?"
In-patient ward rounding, March (Harper Hospital)
Wayne State University-School of Medicine
Preventive Medicine in Public Health
"Ethnic Race Disparities in Health Status"

DMC-Sinai-Grace Hospital
"Hypertension Emergencies and Urgencies"

Wayne State University-School of Medicine
"Advanced Hypertension Management Course"

2002 Wayne State University-School of Medicine
Pathophysiology
Year II Medical Students
Clinical Research Center Lectures Series

Wayne State University-School of Medicine
2nd Annual Update in Internal Medicine - Bay Harbor
"Controversies and New Developments in High-Risk Hypertension: Focus on Diabetes Mellitus, Kidney Disease in AA"

In-patient ward rounding, March (Harper Hospital)

National Kidney Foundation (NKF) Clinical Nephrology Lectures

2001 In-patient ward rounding, January (Harper Hospital)

Wayne State University-Mini Medical School
"Living with Hypertension"

Wayne State University-School of Medicine
Pathophysiology
Year II Medical Students

Wayne State University-School of Medicine
Clinical Perspectives on Vascular Health
Year III Medical Students

Wayne State University-School of Medicine
1st Annual Update in Internal Medicine - Bay Harbor, MI
"An Ounce of Prevention and a Pound of Cure"

American Society of Hypertension (ASH)
Certified Specialist Exam-"Specialist in Clinical Hypertension"

Wayne State University-School of Medicine
Preventive Medicine in Public Health
"Ethnic and Racial Disparities in Health Status

2000 In-patient ward rounding, April (Detroit Receiving Hospital) and June, (Harper Hospital)

OSCE Exam
Third year students
Wayne State University- School of Medicine

"Hypertensive, Urgencies, Emergencies, & Common Secondary Causes"
Cardiology Board Review Course
Wayne State University – School of Medicine

"Diagnosis and Treatment of Hyperaldosteronism"
Endocrinology Review Course
Wayne State University- School of Medicine

Supervise an Endocrinology fellow in clinic one-half day per week.

1982 "Peripheral Vascular Disease/HTN"
Board Review Course for Residents
Wayne State University- School of Medicine

1997 Seventh Annual Physician Assistant Satellite Comprehensive Review Course "Hypertension Update."
Wake Forest University School of Medicine

1996 Physician Assistant Program
Course on "Hypertension."
Wake Forest University School of Medicine

RADIO/TELEVISION APPEARANCE(S):

2019, WTAX "Ask the Expert" Radio show guest appearance

2016, WILL-AM, NPR, The 21st Show, "Precision Medicine Initiative", August 3 (*live taping*)

2015, WICS TV (Springfield, IL), "African Americans Twice as Likely for Sudden Cardiac Arrest", July 21

2010, WJBK, “ASPREE Study: Aspirin and Aging in the Elderly”, July 21

2010, WWJ 950 am, “ASPREE Study: Aspirin and Aging in the Elderly”, July 20

2005, WXYZ, “CVRx Surgical Procedure for Treatment of Hypertension”, July 13 (*live taping)*

2005, CBS, Street Beat with Edward Foxworth, “The American Heart Association and its effect on African-Americans”, January 31 (*live taping*)

2004, UPN/CBS “Hypertension in African Americans”, October 11 *(live taping)*

2004, WLQV 1500 AM “Ask the Doctor” Live radio talk show, October 13

2004, The Dr. Jimmy Womack Show-WGPR 107.5 FM, “Hypertension”

2002, HealthQuest Live, hosted by the publisher of HealthQuest Magazine, Sara Lomax Reese, WURD 800 AM Philadelphia.

2001, The Dr. Jimmy Womack Show-WGPR 107.5 FM, “Hypertension”, December 16

2001, Diane Watkins Show-WHPR 88.1 FM and TV 68, “Hypertension Unchecked Silences Hearts”, [H.U.S.H.], May 25

1999, Newspaper USA Today coverage of discovery that the Angiotensin converting Enzyme gene (II) polymorphism predicts salt-sensitivity in normotensive African-Americans, March 25.

1998, Network Television, Program on the weight loss drug Sibutramine, 48 Hours

FACULTY, PRE-POSTDOCTORAL FELLOWSHIP MENTORING:

Tarek El-Achkar, MD (Assistant Professor, Department of Medicine/Nephrology, Indiana University); mentored him and co-authored a manuscript with him while a Resident at Wayne State.

Philip Levy, MD (Associate Professor of Emergency Medicine, Wayne State University); served as his Robert Woods-Johnson Clinical Scholars Mentor.

Rosalind Peters, RN, MSN, PhD; mentored her and also served on her dissertation committee at Wayne State University College of Nursing (currently an Associate Professor at Wayne State).

Samar Nasser, PAC, PhD; served as chair of her PhD dissertation committee (Physiology) between 9/1/2005 – 1/18/2011, degree conferred 5/31/2011. Dissertation title: “*Effect of Dimethylarginine Dimethylaminohydrolase in the Development of Salt Sensitivity*”

Anna Valina-Toth, MD, PhD; served as chair of her PhD dissertation committee (Physiology) between 6/1/2006 – 6/26/2009, degree conferred 5/3/2011. Dissertation title: *“Vitamin D and Parathyroid Hormone: Relationships with Obesity, Nitric Oxide Metabolites, Oxidative Stress, Blood Pressure, Vascular Function and Salt Sensitivity in African Americans”*

Beth Staffileno, PhD (Associate Professor, Rush University Medical Center, College of Nursing); recruited and mentored her at Wayne State University as a junior faculty prior to her departure for Rush University.

STUDENT AND RESIDENT MENTORING:

2018 Ashley Hill (Certified Nurse Practitioner) mentor for her DNP research project

2016 Sona Fokum, (10th grade student at Illinois Math and Science Academy), mentored her on a project focused on developing a risk prediction score for resistant hypertension.

2016 Bashar Amr, PGY IV (Chief Medicine Resident), mentored him on the project "Higher Systemic Vascular Resistance Impairs Hypertension Control (project took 2nd place at the 26th Annual Southern Illinois University Trainee Research Symposium)

2006 Crystal Simpson, MD, PGY II (St. John's Internal Medicine Program) is doing research rotation focused on identifying the correlate of hypokalemia on subsequent BP responses.

2006 Julie Wright, MD, PGY III Resident research rotation focused on understanding the linkage of albuminuria and hemoglobin/RBC mass in persons with chronic kidney disease independent of estimated glomerular filtration rate.

2006 Krithi Ramesh, MD, PGY II Resident research rotation focused on understanding the impact of glycemic control on longitudinal blood pressure responses in persons with diabetes and hypertension who are pharmacologically treated; also examined the interactive effect of glycemic control with staten therapy on BP responses.

2006 Ratnavalli Pasupulati, MD, PGY II is doing a research project using MedTrace electronic medical record to determine if the BP lowering effect of statins is consistent across a broad range of kidney function.

2006 Hypertension Clinic Resident Physicians Second Clinic Rotation
½ day/week for 6 months
John Tsay, MD, PGY II
Kristen Kingzett, MD, PGY II
Julie Wright, MD, PGY III

2005 Surabel Gebrreselassie, MD, PGY III Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project: Determine the impact of important factors - particularly statin drug therapy and diuretics on the diurnal variation in ambulatory BP in persons referred for measurement of ABPM. Also determine the longitudinal impact of statis and diuretics on the cuff systolic and diastolic BP. (July, 2005)

2005 Kavitha Potluri, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project: Develop an

algorithm for identification of patients who have undergone screening for critical renal artery stenosis with renal artery duplex scanning, and develop an algorithm for identifying patients in MedTrace with critical renal artery stenosis/renovascular hypertension. (September and October, 2005)

2005 Rekha Galla, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project: Develop an algorithm for identification of patients who have undergone screening for critical renal artery stenosis with renal artery duplex scanning, and develop an algorithm for identifying patients in MedTrace with critical renal artery stenosis/renovascular hypertension. (September, 2005)

2005 Neelima Penugonda, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project: Work on the development of a multi-component quality measure for BP care and describe the various properties of the antihypertensive therapeutic index.

2005 Pravati Das, MD, PGY III Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). (Sept. & Oct., 2005)

2005 Jaravaza Tinevimbo, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project: Examine the role of thiazoledindione (TZD's) on longitudinal BP change in persons with diabetes. (Sept., 2005)

2005 Jason Ramos, MD, MS IV, 1 month research rotation (March 2005)

2005 Chalini Chandra, MD PGY-III, 1 month clinical and research rotation (March 2005)

2004-2008 Mentoring-Wayne State University School of Medicine student(s) classes of:

2005- Andrew Weise & Andrew Muskovitz
2007- Mark Zakaria, Ryan Agema, Salman Baig, Michelle Bizon, William Cutriss, & Henrikas Vaitkevicius
2008- Ralph Dilisio, Antonia Jerkins, Manish Kapadia, Dayna Le Platte Patricia Pentiak & Rachel Weisenfild

2004 Howard Blank, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Research project on the rates as well as determinants of blood pressure control in ~500 patients with diabetes mellitus seen in two internal medicine teaching clinics over the course of 1 year.

2004 Lenor Corsino-Nunez, MD, PGY III Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA) project related to the process of care measures and cardiovascular risk factor control in persons with diabetes receiving care. Dr. Corsino-Nunez will also work in the Hypertension clinic for 6 months from July-Jan, 2005.

2004 Crystal Simpson, Medical student Year IV, Wayne State University School of Medicine. Crystal worked on conceptualization and development of clinical research projects involving secondary data analyses of already completed research projects. Worked in the Hypertension clinic three half days a week.

2004 Ivan Hanson, Medical student Year IV. Wayne State University School of Medicine research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project - Describe the overall BP control rates along with the overall characteristics of the hypertensive patients

2003-2007 Mentoring-Wayne State University School of Medicine student(s) classes of:

- 2004- Fadi Eliya
- 2005- Andrew Weise, Andrew Muskovitz & Jeffery Tang
- 2006- John Briles & Jamie Johnson
- 2007- Mark Zakaria, Ryan Agema, Salman Baig, Michelle Bizon, William Cutriss & Henrikas Vaitkevicius

2003 Ali Khan, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA).

2003 Deepak Koul, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project related to the benefits of revascularization in African Americans with critical renal artery stenosis and predictors of a good outcome after angioplasty and stenting in patient with critical renal artery stenosis.

2003 Leonor Corsino, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project related to the comprehensive training support intervention for diabetes [CTSI-D].

2003 Farrukh Koraishy, MD, PGY II Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project related to the study of sodium sensitivity in blacks [SNaP].

2003 Lalitha Rudraiah, MD, PGY III Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project entitled “Alterations in Circulation Blood Pressure Rhythms in Persons with Reduced Kidney Function and/or Proteinuria”.

2002 Abhijeet Goyal, MD, PGY I, Wayne State University-Medical School. Mentor to an internal medicine resident house officer.

2002 Sandhi Nimmagadda, MD, PGY III, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project was to determine the overall prevalence of CVD kidney risk factors and their control amongst persons refereed to our clinic with diabetes mellitus.

2002 Anita Khanna, MD PGY II, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project was to determine the overall impact of the MedTrace system on the effectiveness of management of hypetension amongst persons with reduced kidney function.

2002 Crystal Jones, MD, PGY II, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA) Secondary data analysis of clinical database. Project was focused on identifying predictors of blood pressure response in hypertensive patients with reduced kidney function.

2002 Sidhu Mandeep, MD, PGY III, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Project

NSAID's influence BP responses in persons with hypertension, does this effect differ by level of GFR as well as albuminuria status?

2002 Evans Mokwe, MD, PGY I, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program, (CECA). Project focused on the role of race, per se, in predicting BP response that is independent of indifiable potential confounders? Abstract entitled *"Determinants of Blood Pressure Response to Ace Inhibitor Monotherapy in Hypertensive African Americans and Caucasians"* accepted at the Annual American Society of Hypertension Scientific Meeting, New York, May 13, 2003.

2001 Damanjeet Chugh, MD, PGY II, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Worked on the development of MDRD estimator of Glomerular filtration rate (EGFR) pocket-sized reference card for men and women base on age, gender, race and serum cretinine level.

2001 Karandeep Singh, MD, PGY III, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA), Secondary analysis of clinical database. Abstract entitled-Role of race in predicting blood pressure response independent of identified potential confounders-presented at the ASH meeting, San Francisco, June 8-12, 2002.

2001 Jawaint Rangi, MD, PGY II, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA) Analyses from existing Clinical trial data sets. [ATIME] Accupril Titration Interval Management Study and the Sodium Sensitivity in Blacks Study.

2001 Bede Nnolim, MD, PGY II, Resident research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Development of MDRD Estimate of Glomerular Filtration rate (EGFR) reference card for men and women based on age, race, gender and serum creatinine measurement.

2001 Tarek El-Achkar, MD, PGY II, Resident, research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Performed a secondary data analysis on the National Kidney Foundation Kidney Early Evaluation and Prevention Program database [N=7000] that resulted in a manuscript entitled "Higher Prevalence of Anemia with Diabetes Mellitus in Moderate Kidney Insufficiency" and an abstract accepted for presentation at the American Diabetes Association (ADA), 2002, entitled "Higher Prevalence of Anemia with Diabetes Mellitus in Moderate Kidney Insufficiency."

2001-2002 Hisham Alrefai, MD, Endo Fellow, has worked on two major research projects this year. First, Dr. Alrefai academically performed an analysis on our clinic database that should statin therapy lowers blood pressure significantly in drug – treated hypertensive patients. A second major project was an analysis of this same clinical database to delineate the impact of non-selective non-steroidal anti-inflammatory drugs and selective COX-2 inhibitors on blood pressure response to anti hypertensive therapy by level of kidney function in drug-treated hypertensive.

2001 NIH-Charles R. Drew University of Medicine & Science National Summer Mentoring Program- Michael McIver 12th grade, University Liggett High School and Natalie Taliaferro 12th grade Mercy High School, Project title: The Relationship of

Kidney Function and Cardiovascular Risk Factors in Men and Women at Risk for Kidney Disease.

2000 Rob Thornburg, 4th year student, Wayne State University. Secondary analysis of Hypertension Clinical database. Abstract entitled *"Factors Correlated to Blood Pressure Response in Hypertensive Patients with Type 2 Diabetes Mellitus"*, accepted for presentation at the American Society of Hypertension, Scientific meeting, San Francisco, CA 2001.

2000 Karl Duncan, MD, PGY II, Resident, research rotation in the Cardiovascular Epidemiology and Clinical Applications Program (CECA). Secondary analysis of Hypertension Clinical database. Abstract entitled*, "The Influence of Urinary Albumin Excretion and Estimated Glomerular Filtration Rate on Blood Pressure Response in Drug-Treated Hypertensive Patients in an Academic Hypertension Clinic",* accepted for presentation at the 2001 American Society of Hypertension Scientific meeting, San Francisco, CA. A manuscript from this abstract is nearly complete.

2000 Edouard Daher, MD, faculty mentee was successful in securing internal "Seed Grant" funding during calendar year 2000.

2000 Karandeep Singh, MD, PGY II, Resident, research rotation in the Cardiovascular Epidemiology and Clinical Applications program (CECA). He performed a secondary analysis of our clinical database.

1998-2000 Navdeep Mann, MD, PGY III, Resident, completed a five week research rotation under my tutelage. Co-authorship of a book chapter on renal artery stenosis and general research mentoring

2000 Rosalind Peters, RN, MSN, Doctoral Student: Member of Ph.D., Dissertation Committee Wayne State University College of Nursing Center for Health Research. Co-authored peer-reviewed manuscript together.

1999-2002 Joanne Studley, Wayne State University, Undergraduate Student, Project: Secondary data analysis of the "Treatment of Low HDL Cholesterol (TOLC) dataset."

1997 Charles Holmes, fourth-year Wayne State University Medical Student, Project: Secondary data analysis of the NHLBI-funded [SNaP] Sodium and Blood Pressure dataset; "Interaction of Obesity and the Renin-Angiotensin Aldosterone-Kinin System in Mediating Salt-Sensitivity in Normotensive African-Americans."

1997 Jyothy John Puthumana, third-year Wayne State University Internal Medicine Resident Project: Secondary data analysis of the SNaP dataset; "Relationship of Obesity to Blood Pressure Response to Dietary Sodium Manipulations in Normotensive African-Americans"

GRANTS AND CONTRACTS SUPPORT (ACTIVE):

1. Title: Chronic Renal Insufficiency Cohort Study (CRIC)
   Funding: University of Michigan NIDDK 5K24DK062234 UM Subcontract ($613,942)
   Purpose: NIH-Sponsored, multicenter, prospective cohort study designed to determine the risk factors for accelerated decline in renal function and to evaluate the

incidence and risk factors for cardiovascular disease (CVD) in patients with chronic renal insufficiency (CRI).
Period: 05/04-ongoing
Role: Co-Investigator-Wayne State University site
FTE: 0%

2. Title: Bayer Protocol 16244: A Randomized, double-blind, placebo-controlled, parallel-group, multi-center, event-driven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease.
Funding: Bayer
Period: 12/18/2015—ongoing
Role: Principal Investigator – Southern Illinois University
FTE: 5%

3. Title: A Phase 3 randomized, open-label, active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of GSK1278863 compared to darbepoetin alfa
Funding: Glaxo Smith Kline (approx. $210,000)
Purpose: To demonstrate whether GSK1278863 is non-inferior or superior to darbepoetin alfa for cardiovascular safety
Period: 04/2016-Ongoing
Role: Principal Investigator
FTE: 5%

4. Title: Southern Illinois University – Illinois Hospital Association Hypertension TeleECHO Clinic Grant
Funding: Center for Medicaid Services (CMS)/Illinois Hospital Association (AHA)
Purpose: To develop and deliver a hypertension management curriculum to primary care providers in southern and central Illinois using interactive case-based approaches via teleconferences
Period: 2017 – 2019
Role: Principal Investigator
FTE: 7.5%

5. Title: Bayer Protocol 17530: A Randomized, double-blind, placebo-controlled, parallel-group, multi-center, event-driven Phase III study to investigate the efficacy and safety of finerenone on the reduction of cardiovascular morbidity and mortality in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease in addition to standard of care.
Funding: Bayer
Period: 12/18/2015—ongoing
Role: Principal Investigator – Southern Illinois University
FTE: 5%

6. Title: CALM-2: Controlling and Lowering Blood Pressure with the MobiusHD
Funding: Vascular Dynamics
Period: 3/16/2018 – ongoing
Role: Principal Investigator – Southern Illinois University
FTE: 3%

7.	Title:	NEW-HOPE: A Phase 2, Open-Label, dose-Titrating Safety and Efficacy Study of QGC001 Administered Orally, Twice Daily, Over 8 Weeks in Hypertensive Overweight Subjects of Multiple Ethnic and Racial Groups in the United States.
	Funding:	Quantum Genomics
	Period:	1/22/2018 – ongoing
	Role:	Principal Investigator – Southern Illinois University
	FTE:	3%
8.	Title:	RADIANCE-HTN: A study of the ReCor Medical Paradise System in Clinical Hypertension
	Funding:	ReCor Medical
	Period:	5/15/2018 – ongoing
	Role:	Principal Investigator – Southern Illinois University
	FTE:	3%
9.	Title:	PRECISION: Multi-center, blinded, randomized, PaRallEl-group, Phase 3 study with aprocItentan in Subjects with ResIstant Hypertension (RHT).
	Funding:	Idorsia
	Period:	Anticipated 7/2018 – ongoing
	Role:	Principal Investigator – Southern Illinois University
	FTE:	3%
10.	Title:	SIU Hypertension Registry
	Funding:	SIU Internal Funding
	Period:	3/20/2020 –
	Purpose:	To do extensive non-invasive vascular and body composition phenotyping in several high-risk hypertension subgroups (resistant & refractory hypertension, women with history of any hypertensive disorder of pregnancy, and patients with primary aldosteronism); these cohorts will be followed longitudinally and compared to their natural comparator groups to better understand how these conditions mediate high vascular risk.

GRANTS AND CONTRACTS (Pending Review):

1.	Title:	Biological Screening for Medication Adherence in SPRINT (R21HL153658)
	Funding:	NIH
	Purpose:	To directly measure antihypertensive drug metabolites in stored SPRINT study samples to understand their relationship to blood pressure responses, serious adverse events (SAEs) and CVD-renal study outcomes.
	Period:	7/1/2020 – 6/30/2022
	Role:	Principal Investigator
	FTE:	7.5%
2.	Title:	Impact of Objectively Measuring Antihypertensive Medication Adherence on CVD-Renal/Mortality Attributable to Hypertension Phenotypes in CKD Patients
	Funding:	NIH/CRIC Opportunity Pool
	Purpose:	To directly measure antihypertensive drug metabolites in stored CRIC study samples to understand the extent of adherence to antihypertensive medications in CKD patients and also to determine the impact of medication

on CVD-renal and mortality risk estimates to various hypertensive phenotypes.
Period: 12/31/2020 – 1/01/2021
Role: Principal Investigator
FTE: 0.24 calendar months

GRANTS AND CONTRACTS (Submitted but Unfunded):

1. Title: Effect of Vitamin D in Pre-diabetes and Obesity
Funding: NIDDK
Purpose: To determine the relative impact of high-dose Vit D (3600IU/D) relative to low-dose (500IU/D) on visceral adiposity, glycemic control, inflammation and traditional CVD risk factors in obese normotensive African Americans with pre-diabetes.
Period: 9/1/2013 – 8/31/2017 (Not funded)
Role: Principal Investigator
FTE: 30%

2. Title: Maximizing Hypertension Treatment Effectiveness (MHyTE) study (R01NR019474)
Funding: NINR
Purpose: A cluster randomized trial testing whether a distance learning intervention aimed at rural physicians and nurses improved BP lowering; hypertension related process of care measures, professional competence the intervention uses the flipped classroom approach. (Grant was administratively triaged because professional education was outside the scope of their funding priorities)
Period: 7/1/2020 – 6/30/2025
Role: Principal Investigator
FTE: 7.5%

GRANTS AND CONTRACTS (COMPLETED):

1. Title: Adjunct Vitamin D Therapy with Vitamin D as a Means to Reduce Disparities Subclinical Target-Organ Cardiac Damage Among Vulnerable Hypertensive Patients.
Funding: NIH/NIMHD (1R01 MD005849-01A1) ($1,250,000)
Purpose: Vitamin D deficiency may be an important contributor to racial differences in hypertensive heart disease but whether adjunct vitamin D therapy provides benefit is unknown. We seek to ascertain the effect of adjunct vitamin D therapy on left ventricular hypertrophy (primary aim), myocardial fibrosis and central vascular function (secondary aims) at one-year using a placebo controlled, randomized design.
Period: 03/01/11-02/28/16
Role: Co-investigator
FTE: 5%

2. Title: Aspirin in Reducing Events in the Elderly (ASPREE)
Funding: National Institute on Aging/Berman Center for Outcomes and Clinical Research Subcontract ($2,088,000)

	Purpose:	The purpose of this project aims to assess whether aspirin can not only prolong life but help provide a life free of physical disability and/or dementia for healthy older people.
	Period:	04/01/2010 through 03/31/2017
	Role:	Principal Investigator-Wayne State University site
	FTE:	5%
3.	Title:	Vitamin D Augmentation of Tekturna® (Aliskiren) in Hypertension (VDATH)
	Funding:	Novartis Pharmaceutical Corporation ($512,733)
	Purpose:	The overarching hypothesis is that African Americans with hypertension have an overactive renin angiotensin system at the tissue level and a metabolic milieu (high oxidative stress and depressed nitric oxide metabolism), both conceivably as a consequence of or at least significantly influenced by, vitamin D deficiency. We posit that this results in the lesser average BP response to monotherapy with renin angiotensin system blockers. (Investigator initiated; sponsor terminated study after enrolling 10 patients because of safety concerns with aliskiren emanating from another trial)
	Period:	01/01/2011 through 07/31/2012
	Role:	Principal Investigator
	FTE:	5%
4.	Title:	Community Network Program for Older Underserved African American Adults
	Funding:	NIH (NCI) $2,580,746
	Purpose:	To propose an active and comprehensive community-based program to reduce disparities of breast, prostate, colorectal, and lung cancer in older African American Adults in metropolitan Detroit.
	Period:	04/01/05 through 03/31/10
	Role:	Co-Investigator
	FTE:	10%
5.	Title:	A Prospective, Randomized, Open-Label Clinical Trial to Evaluate the Effect of Tekturna® (Aliskiren), Angiotensin Inhibitors, Diuretics, and Calcium Channel Blockers on Coronary Flow Reserve in Patients with Type II Diabetes and Hypertension
	Funding:	Novartis Pharmaceutical Corporation/William Beaumont Hospitals Subcontract $53,448
	Purpose:	To evaluate the effects of a Tekturna (aliskiren) on coronary flow reserve in diabetic, hypertensive patients being treated with an ACE inhibitor and amlodipine.
	Period:	04/01/2010 through 03/31/2011
	Role:	Principal Investigator
6.	Title:	Mechanisms of Meditation in Hypertension in Blacks
	Funding:	NIH-NHLBI
	Institution:	Maharishi University of Management Research Institute/Center for Natural Medicine and Prevention
	Purpose:	To develop research infrastructure to enhance the conduct of multi-disciplinary, disparities related research.
	Period:	2/2008-2012
	Role:	Data Safety and Monitoring Board Member
	FTE:	0%

7. Title: Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL)
Funding: National Institute of Health/University of Toledo
Subcontract $26,925
Purpose: A prospective, multi-center, unblinded, two-arm, randomized trial to test the hypothesis that medical therapy with stenting of significant renal artery stenoses in patients with systolic hypertension reduces the incidence of adverse cardiovascular and renal events compared with medical therapy alone.
Period: 9/06 through 12/12
Role: Principal Investigator-Wayne State University site
FTE: 1%

8. Title: Center for Urban and African American Urban Health.
Funding: National Institute of Environmental Health Science [ES-012395] $5,946,924
Purpose: Understanding the mechanisms operating at multiple levels (environment, lifestyle, physiology, genetics) mediating known disparate chronic conditions and their precursors and to identify preventive strategies and therapeutic approaches that might alleviate the disproportionate burden of disease
Period: 09/01/2003 through 05/31/2008
Role: Principal Investigator
FTE: 25 %

- Principal Investigator Administrative Core ($543,876)
  10% Effort
- Principal Investigator Individual R01 Project:
  Obesity, Nitric Oxide, Oxidative Stress and Salt Sensitivity
  ($483,796) 15% Effort

9. Title: Research Enhancement Grant
Funding: Wayne State University Office of the President & Provost $1,800,000
Purpose: To develop research infrastructure to enhance the conduct of multi-disciplinary, disparities related research.
Period: 11/2004-10/2007
Role: Principal Investigator
FTE: 0%

10. Title: Comprehensive Treatment and Support Intervention [CTSI-D] for Diabetes
Funding: International Society of Hypertension in Blacks/Association of Teachers in Preventive Medicine/Center for Disease Control $402,756.00
Purpose: Intervention to provide a comprehensive, evidence-based decision support to internal medicine house-officers and attendings using the MedTrace electronic medical clinical decision support system at two internal medicine resident clinics at major academic centers.
Period: 1/2002 through 12/2005
Role: Principal Investigator
FTE: 13%

11. Title: Nurse-Managed Blood Pressure Telemonitoring with African Americans
Funding: National Institute of Health $1,490,000.00
Purpose: To compare usual care only with home telemonitoring/telecounseling plus usual care to determine which has the greatest effect on change In blood pressure form baseline; and to examine why the intervention works to control

blood pressure by examining selected mediators, ie, dietary habits, physical activity level, weight loss, reduced alcohol intake habits, physical activity level, weight loss, reduced alcohol intake, compliance with an antihypertensive medication regimen, and contact with primary care provider.
Period: 09/2000 through 09/2005
Role: Co-Investigator
FTE: 6%

12. Title: Secondary Prevention of Small Subcortical Strokes (SPS3)
Funding: University of Texas Health Science Center NIH-NINDS
Purpose: To define efficacious therapies for cerebral small artery disease and its two most common clinical manifestations: small subcortical strokes (S3) (a.k.a. lacunar strokes) and cognitive decline (vascular dementia)
Period: 03/2003-02/2004
Role Investigator
FTE: 10%

13. Title: Multi-center, Double-blind, Randomized Placebo-controlled Parallel Group
Funding: MSP Singapore Co., LLC c/o Merck & Co., Inc.
Purpose: 6-week study to evaluate the efficacy and safety of ezetimbe 10/day when added to ongoing therapy with a statin verses statin therapy alone, in patients with hypercholesterolemia who have not reached National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III target LDL-cholesterol level.
Period: 05/20/2002 through 02/01/ 2003
Role: Principal Investigator
FTE: 5%

14. Title: A 6-week Randomized, Open-label, Comparative Study to Evaluate the Efficacy and Safety of Rosovastatin and Atorvastatin in the Treatment of hypercholestorolemia in African-American subjects (ARIES).
Funding: Astra Zeneca Pharmaceutical
Purpose: Compare the efficacy of 2 doses of rosovastatin (10 & 20 mg) with 2 doses of atorvastatin (10 & 20 mg) in African-American Subjects with high cholesterol by measuring the percent change in LDL-C from base line after 6 weeks of treatment.
Period: 01/02/2002 through 05/15/2003
Role: Principal Investigator
FTE: 5%

15. Title: A Randomized, Multicenter, Double-Blind, Parallel group Study to Determine the Safety and Efficacy of Lotrel versus Enalapril in the Treatment of Hypertension in an African-American Population with Type 2 Diabetes
Funding: Novartis Pharmaceuticals $42,460.00
Purpose: Determine the safety and effectiveness of lotrel (a combination of enalapril in the treatment of high blood pressure (hypertension) in African American men and women who have Type II Diabetes.
Period: 12/2/2002 through 10/30/2003
Role: Principal Investigator
FTE: 5%

16. Title: A Multicenter, Open-label, Flexible Dose Escalation Study to Evaluate the

		Correlation between event Log Parameters, Self Esteem/Overall Relationships Efficacy of Viagra ®) (Sildenifil Citrate) in Men with Erectile Dysfunction	
	Funding:	Pfizer Pharmaceuticals	$11,437.50
	Purpose:	To determine the correlation between changes in the self-esteem domain score of the Self-Esteem/Overall Relationship Questionnaire (SEAR) and measures of intercourse success (obtained from patient event logs), and improved erectile function (obtained from the Erectile Function (EF) domain of the (IIEF) in male outpatients with erectile dysfunction.	
	Period:	5/2002-12/2002	
	Role:	Principal Investigator	
	FTE:	4%	
17.	Title:	The DREAM (Diabetes Reduction Assessment with Raimpril and Rosiglitizone Medication) Trial	
	Funding:	Hamilton Health Sciences Corp.	$68,250.00
	Purpose:	The DREAM trial is designed to determine if treatment with either ramipril and/or rosiglitizone will prevent or reduce the incidence of diabetes in people with impaired glucose tolerance (IGT) or impaired fasting glucose (IFG).	
	Period:	6/4/2002-12/31/2007	
	Role:	Principal Investigator	
	FTE:	5%	
18.	Title:	A 12-Week, Multicenter, Double Blind, Parallel, Forced-Titration Study of Teveten Eprosartan Mesylate; SK&F 108566-J) at Doses of 600 mg and 1200mg Given Once Daily and Enalapril (20mg and 40mg) Given Once Daily Compared to Placebo in African-American Patients with Essential Hypertension SitDBP>95 and <109 mmHG and SitSBP >145 and <179 mmHg) During Periods With and Without Supplemental Salt Intake (100mmol/day) Protocol 155.	
	Funding:	SmithKline Beecham Pharmaceuticals	$42,480
	Purpose:	To determine the blood pressure lowering efficacy of a novel angiotensin receptor antagonist in African-Americans, to determine the influence of dietary sodium administration on the antihypertensive efficacy of this agent in stage 1-2 hypertensives.	
	Period:	1998-ongoing	
	Role:	National Principal Investigator of this Multicenter Clinical Trial	
19.	Title:	Sodium and Angiotensin Peptide Protocol [SAAP] A Pilot Study	
	Funding:	Internal Funding	
	Purpose:	Evaluating the impact of dietary sodium consumption on both ambulatory and cuff blood pressure, arterial compliance and to correlate sodium consumption with markers of target-organ-damage in African American women with normal to high blood pressure.	
	Period:	1998	
	Role:	Principal Investigator	
20.	Title:	Hemodynamic Determinants of the Blood Pressure Response to Accumulated Physical Activity in African American Women	
	Funding:	Harper Hospital Foundation	$24,981
	Purpose:	To investigate the hemodynamic and hormonal effects of moderate intensity physical activity on sedentary African-American women with high-normal to stage 1 blood pressure evaluation.	
	Period:	1998-99	

Role: Principal Investigator

21. Title: Evaluation of the Antihypertensive Efficacy, Safety, and Tolerability of Candesartan Cilexetil in Comparison to Amlodipine: A Multicenter, Double Blind, Randomized, Parallel Group, Forced Titration Study (CASTLE Study) Protocol # 176
Funding: Astra Merck $30,000
Purpose: Evaluate the efficacy, safety and tolerability of Candesartan cilexetil in hypertensive
Period: 1998
Role: Principal Investigator

22. Title: A Multicenter, Double-blind, randomized, parallel group, placebo-controlled study to investigate the antihypertensive efficacy and safety of Losartan in African Americans with mild-to-moderate hypertension (protocol 172)
Funding: Merck & Company
Purpose: To investigate the antihypertensive efficacy of losartan in African Americans with mild-to-moderate hypertension
Period: 1998
Role: National Principal Investigator of this Multicenter Clinical Trial

23. Title: A Multicenter, Single-Blind Trial Evaluating the Efficacy of Amlodipine in Patients with Severe Hypertension R0515
Funding: Pfizer, Incorporated $39,760
Purpose: Evaluate efficacy of amlodipine in patients with severe hypertension
Period: 1997
Role: Principal Investigator (#H09 16 97 (MO1)-FB)

24. Title: Efficacy of Candesartan Cilexetil in Hypertensive Black Patients: A Double Blind, Randomized, Placebo Controlled, Parallel Group Design Study with an Open Label, Long Term Extension (ABC, Protocol 140)
Funding: Astra Merck $60,000
Purpose: To evaluate the efficacy of Candesartan in African Americans with mild-to-moderate hypertension.
Period: 1998
Role: Principal Investigator

25. Title: Accupril Titration Interval Management Evaluation Trial (ATIME Study, Protocol 906-394)
Funding: Parke-Davis $555,445
Purpose: To provide data coordination services for Antihypertensive drug trial involving 3000 participants at 400 clinical sites in the United States
Period: 1996-1998 (completed)
Role: Principal Investigator (Investigator Initiated)

26. Title: “RFA, Vascular Disease Academic Award
Funding: NHLBI HL-94-015/k07 $561,660
Purpose: To promote the discipline of vascular medicine through teaching, clinical, and research activities.
Period: 1995-00
Role: Co-Principal Investigator/Medical Director

27. Title: "A Randomized Double-Blind, Outpatient, Dose-Titration Trial of ANA-756 vs. Atenlol (Beta-Blocker) In Patients with Essential Hypertension
Funding: Wyeth-Ayerst Research
Purpose: To compare the safety and effectiveness of increasing doses of ANA-756 and atenolol (beta-blocker already on the market) on the change in blood pressure in patients with essential hypertension.
Period: 1995-95
Role: Co-Principal Investigator

28. Title: "Study of Coronary Heart Disease Risk Factors in Young Adults (CARDIA)"
Funding: NHLBI/NIH NO1 HV487048 $2,471,875
Purpose: To monitor the evolution of cardiovascular risk factors and their determinants in a biracial cohort of young adults.
Period: 1993-94
Role: Principal Investigator

29. Title: "Women's Health Trial"
Funding: NIH - N01 WH3 2101 $10,863,212
Purpose: A randomized, controlled, multicenter trial designed to evaluate the feasibility of recruiting women of different socio-economic status and minority groups and to determine whether these women can achieve and maintain low-fat eating habits.
Period: 1993-95
Role: Co-Principal Investigator (Dr. Grimm, Principal Investigator)

30. Title: "Multicenter Efficacy and Tolerability Study Comparing Proscar (Finasteride) and Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia in a Primary Care Setting (PROSCAR Study)"
Funding: Merck Human Health $37,500
Purpose: To examine the efficacy and tolerability of therapy with Proscar (finasteride) in patients with moderate to severe symptomatic benign prostatic hypertrophy.
Period: 1993-95
Role: Principal Investigator

31. Title: "Healthy Eating and Lifestyle Program (HELP)"
Funding: $3,000
Purpose: Attempt to decrease the prevalence of cardiovascular risk factors in two predominantly African-American church congregations through peer counseling.
Period: 1993-94
Role: Principal Investigator

32. Title: "Sodium Sensitivity in Blacks" (SNaP)
Funding: NIH/NHLBI R01 - HL - 46630 - 01A1 $1,394,250
Purpose: To identify factors which predict a pressor effect with sodium chloride administration in African Americans.
Period: 1992-94
Role: Co-Principal Investigator (Dr. Grimm, Principal Investigator)

33. Title: "Craniomandibular Disorders: Long-Term Outcome Study"
Funding: NIH $502,680
Purpose: To compare several different approaches to the management of TMJ disorders.
Period: 1992-97

	Role:	Co-Principal Investigator, Epidemiologist	
34.	Title:	"Arterial Disease Multiple Intervention Trial (The ADMIT Study)"	
	Funding:	NIH/NHLBI N01 HC25111	$485,192
	Purpose:	To evaluate treatment and prevention strategies for atherosclerosis, cardiovascular disease clinical centers	
	Period:	1992-95	
	Role:	Assistant Project Director (Dr. Hunninghake, Principal Investigator)	
35.	Title:	"Treatment of Low HDL Cholesterol (TOLC) Study	
	Funding:	Innovite - Pharmaceuticals	$38,000
	Purpose:	To determine the relative efficacy of Enduracin, a modified-release niacin preparation, versus Criptalline (unmodified) niacin for raising HDL cholesterol levels in nonsmoking men and women with low HDL (<40 mg/dl)	
	Period:	1991	
	Role:	Principal Investigator (Investigator initiated)	
36.	Title:	"Ambulatory Blood Pressure Study in USA Blacks and Liberian Immigrants"	
	Funding:	BRSG, University of Minnesota	$6,792
	Purpose:	To make preliminary observations regarding ambulatory blood pressure patterns in United States Blacks and Liberian Immigrants to obtain preliminary estimates of repeatability ambulatory blood pressure measurements in these unique populations.	
	Period:	1991-92	
	Role:	Principal Investigator	
37.	Title:	"Feasibility of Reduction of Dietary Sodium in Black Participants"	
	Funding:	BRSG	$11,075
	Purpose:	To establish the methodology and demonstrate feasibility of this sodium reduction for an NIH proposal on the evaluation of the effect of dietary sodium intervention on blood pressure in Blacks and Whites.	
	Period:	1990-91	
	Role:	Co-Principal Investigator	
38.	Title:	"Lipid and Thiazide Study (LATS)"	
	Funding:	Reuben Miller Cardiovascular Fund	$6,000
	Purpose:	To support my ongoing research on the effects of thiazide diuretics on cholesterol distribution across LDL cholesterol subclasses.	
	Period:	1989-90	
	Role:	Principal Investigator	
39.	Title:	"Multicenter Isradipine/Diuretic Atherosclerosis Study (MIDAS)"	
	Funding:	Sandoz Pharmaceuticals	$759,348
	Purpose:	To monitor the rate of progression of medial intimal thickness in hypertensive men and women with extracranial carotid artery plaque who were randomized a thiazide diuretic or isradipine, a dihypropyridine calcium antagonist.	
	Period:	1988-92	
	Role:	Co-Principal Investigator (R. Grimm, Principal Investigator)	
40.	Title:	"The Effect of Thiazide Diuretics on LDL Cholesterol Subclasses"	
	Funding:	University of Minnesota School of Public Health Biomedical Research Grant; #BRSG 0696-5725-95	$11,989

	Purpose:	To assess the influence of thiazide diuretics on the distribution of cholesterol across LDL cholesterol subclasses.
	Period:	1989-91
	Role:	Principal Investigator
41.	Title:	"Northeast Oklahoma City Cholesterol and Cardiovascular Risk Factor Screening and Education Program"
	Funding:	University of Oklahoma Health Sciences Center Biomedical Research Support Grant $6,700
	Purpose:	To conduct a church-based cholesterol education program.
	Period:	1987-88
	Role:	Co-Principal Investigator (W. Wiist, Principal Investigator)
42.	Title:	"Lovastatin Dose-Ranging Multicenter Study in Patients with Type II Hypercholesterolemia, Total Cholesterol 240-300 mg/dl With or Without Other Risk Factors and With and Without Evidence of Coronary Disease"
	Funding:	Merck Sharp and Dohme $25,000
	Purpose:	Obtain Lovastatin safety data
	Period:	1987-1988
	Role:	Principal Investigator
43.	Title:	"Treatment of Mild Hypertension Study (TOMHS)"
	Funding:	NHLBI/NIH R01 HL34767 $1,733,971
	Purpose:	To determine optimal treatment of adults with mild diastolic hypertension (90-99 mmHg).
	Period:	1985-1991
	Role:	Co-Investigator

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18. **Flack JM**, Grimm RH, Lewis CB, Grandits G, Elmer P, Prineas R, Schoenberger J. "Comparison of response to low dose antihypertensive medication between black and white participants in the treatment of mild hypertension study (TOMHS)." Presented at the Seventh

International Interdisciplinary Conference on Hypertension in Blacks, Atlanta, Georgia, May 26-31, 1992.

19. Elmer PJ, **Flack JM,** Grimm RH, Gonzalez N, Cox J, Herbrandson M, Hillman D, Laing B. "Feasibility of diet sodium reduction in middle-aged Blacks." Presented at the Seventh International Interdisciplinary Conference on Hypertension in Blacks, Atlanta, Georgia, May 26-31, 1992.

20. Gidding SG, Gardin J, Xie X, **Flack JM,** Manolio T, Sedlacek C. "The prevalence of echocardiographically diagnosed cardiac disease in an asymptomatic population: The CARDIA Study" Presented at the American Heart Conference, New Orleans, Louisiana, November 16-19, 1992.

21. **Flack JM,** Liu K, Nelson E, Bild D, Hardin M, Hulley S. "Relationship of insulin level to 5-year risk of hypertension in a bi-ethnic cohort of young adults: The CARDIA Study" Presented at the American Heart Conference, Santa Fe, New Mexico, March 17-20, 1993.

22. **Flack JM,** Yunis C, Keenan J, Sprafka JM, Grimm R, Levin R, Sisson L. "Treatment of low high density lipoprotein (HDL) cholesterol (TOLC) Study" Presented at the 34th Annual Conference on Cardiovascular Disease Epidemiology and Prevention American Heart Association, Tampa FL, March 16-19, 1994.

23. Prisant LM, Khoury S, **Flack JM,** Carr AA, Sowers JR, Neuwirth R. "Biochemical changes of MIDAS patients according to treatment and race." Presented at the Ninth Interdisciplinary Conference on Hypertension in Blacks, June 22-26, 1994.

24. Prisant LM, Nichols F, **Flack JM,** Carr AA, Mercuri M, Neuwirth R, Bond G. "Risk factors correlated of carotid intima-media thickness (IMT) of MIDAS patients." Presented at the Ninth Interdisciplinary Conference on Hypertension in Blacks, June 22-26, 1994.

25. Prisant LM, **Flack JM,** Carr AA, Neuwirth R. "Antihypertensive effects in black and white MIDAS patients" Presented at the Ninth Interdisciplinary Conference on Hypertension in Blacks, June 22-26, 1994.

26. Prisant LM, Nichols F, **Flack JM,** Carr AA, Neuwirth R, Mercuri M, Bond G. "Change in carotid intima-media thickness (IMT) of MIDAS patients." Presented at the Ninth Interdisciplinary Conference on Hypertension in Blacks, June 22-26, 1994.

27. Cohen JD, Edwards A, Cooper R, **Flack JM,** D'Agostino R, Grimm RH, Grundy SM, Kannel WB, Higgins M, Kronmal RA, Hill M, Lee ET. "Workshop on assessing risk for coronary heart disease." Presented for the National Heart, Lung, and Blood Institute, National Institutes of Health, January 19-20, 1999.

28. Weinberger M, Denke M, **Flack JM,** Hunt S, Sacks F, Kotchen T, McCarron D, Svetkey L. Workshop on Sodium and Blood Pressure. "Response to dietary sodium and other nutrients." Presented at the Bethesda Marriott Hotel for the National Heart, Lung, and Blood Institute, National Institutes of Health, January 28-29, 1999.

29. Patel NR, Alrefai HA, Ohmit S, Nasser S, **Flack JM**. Benefits of revascularization in African Americans with critical renal artery stenosis. Presented at International Society of Hypertension in Blacks and Minorities (ISHIB) at Miami, FL;June 8-12, 2002.

30. Alrefai HA, Rangi J. Ohmit S, Nasser S, Dudley A, **Flack JM.** Total cholesterol and statins affect blood pressure response to antihypertensive drugs in hypertensive patients. Presented at The Endocrine Society's 84th Annual Meeting in San Francisco, CA;June 19-22, 2002.

31. Nnolim B, Ohmit SE, Nasser S, Hedquist LA, **Flack JM**. The Glomerular Filtration Rate (GFR) Estimator in Clinical Practice. Presented at the American College of Physicians American Society of Internal Medicine (ACP-ASIM) Michigan Chapter at Ypsilanti, MI;May 17, 2002.

32. Koul D, Dudley AI, Shafi T, Nasser S, Crook E, Spears R, **Flack JM**. Outcomes after renal angioplasty and stent placement in hypertensive African Americans with critical renal artery stenosis. Presented at the American Society of Hypertension 19th Annual Scientific Meeting, 2004.

33. Gebreselassie SF, Lai Z, Ohmit S, Tsilimingras D, Nasser S, Dews P, Britton M, **Flack JM**. Factors influencing blood pressure level and diurnal blood pressure variation in patients with complex hypertension. Presented at the American Heart Association 7th Scientific Meeting on Quality of Care and Health Outcomes on Cardiovascular Disease and Stroke: May 8-9, 2006.

34. Blank H, Lai Z, Anderson D, Guo X, Ohmit S, Nasser S, Dews P, **Flack JM**. Hypertension control and use of renin-angiotensin systems therapies in persons with diabetes and hypertension. Presented at the American Society of Hypertension Inc. 21st Annual Scientific Meeting and Exposition in New York, NY: May 16-20, 2006.

35. Das P, Lai Z, Ohmit S, Nasser S, Dews P, **Flack JM**. The influence of Albuminuria on longitudinal blood pressure (BP) response to antihypertensive drug therapy. Presented at the American Society of Hypertension,Inc. 21st Annual Scientific Meeting and Exposition in New York, NY; May 16-20, 2006.

36. Tinevimbo J, Lai Z, Nasser S, Dews P, Britton M, **Flack JM**. Effect of longitudinal blood pressure change and hypertension control in predominantly African American patients with hypertension and type 2 diabetes. Presented at the American Society of Hypertension, Inc. 21st Annual Scientific Meeting and Exposition in New, NY; May 16-20, 2006.

37. Levine D, Anderson D, Ohmit S, Corsino L, Guo X, Lai Z, Nasser S, Britton M, Dews P, **Flack J**. Comprehensive training and support intervention for diabetes (CTSI-D). Presented at the International Society of Hypertension in Blacks 21st Annual International Interdisciplinary Conference on Hypertension and Related Cardiovascular Risk Factors in Ethnic Populations in Atlanta, GA:June 23-26, 2006.

38. Penugonda N, Lai Z, Tsilimingras D, Britton M, Nasser SA, Dews P, **Flack JM.** A multi-component hypertension quality of care score predicts longitudinal blood pressure responses and hypertension control in a hypertensive cohort. Presented at the American Heart Association Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke in Washington DC;May 9-11, 2007.

39. Potu S, Britton M, Tsilimingras D, Yoo Wonsuk, Quah R, Lai Z, Liu X, Nasser SA, Goel A, Dews P, **Flack JM**. The effect of Cox-2 selective NSAIDs on longitudinal blood pressure change according to the level of kidney function. Presented at the American Society of

Hypertension 22nd Annual Scientific Meeting and Exposition in New York, NY;May 17-21, 2007.

INVITED PRESENTATIONS (Selected Presentations):

1. African-American International Collaborative Research Scientists Symposium. International Society on Hypertension in Blacks. Zimbabwe, Africa, February 24-28, 1992.

2. Case Western Reserve University, University Hospitals Janice Douglas-David Satcher Address, "Strategies in managing the African American hypertensive with multiple cardiovascular risk factors" Cleveland, Ohio, November 4, 1992.

3. "Salt and high blood pressure: unanswered questions and unquestioned answers." American Heart Association Twentieth Science Writers Forum. January 17-20, 1993.

4. "Is hypertension really different in blacks and the role of genetics in hypertension?" Preventive Cardiology Symposium, Morehouse School of Medicine. March 6, 1993.

5. "The evidence that treatment of hypertension works." Plenary Session VI Eight International Interdisciplinary Conference on Hypertension in Blacks. Yaounde, Cameroon, Africa, April 8, 1993.

6. "Salt and blood pressure: unanswered questions and unquestioned answers." The First Annual Department of Medicine House Staff Research Conference, University of Oklahoma Department of Internal Medicine, April 16, 1993.

7. "Role of Sodium," Plenary Session X, Symposium: Primary Prevention of Hypertension. American Heart Association Annual Scientific Session, Atlanta, Georgia, November 10, 1993.

8. Role of Angiotensin II in Cardiovascular Pathology. "Angiotensin II antagonists in salt-sensitive hypertension." Satellite Symposium 67th Scientific Sessions American Heart Association, Dallas, Texas, November 13, 1994.

9. Outcomes Management: Conception through Implementation. "Outcomes management: lessons from TOMHS." Miami Beach, Florida, December 7, 1994.

10. Visiting Professorship in Preventive Medicine "Hypertension and the evolving interface of public health, clinical management and managed care." Houston, Texas, March 7-9, 1995.

11. State of the Art Lecture "Systemic hypertension." American College of Cardiology. New Orleans, Louisiana, March 21, 1995.

12. Lectures at AHEC regional hospitals. "Evaluation of renal artery hypertension" North Wilkesboro, North Carolina, April 4, 1995.

13. Oklahoma Heart Research & Education Foundation. "Current trends in therapy, how aggressively should we be treating our patients?" Tulsa, Oklahoma, May 5, 1995.

14. Region III-National Medical Association Annual Conference "Treatment of hypertension: the state of the art." Mobile, Alabama, May 20-21, 1995.

15. American Heart Association Annual Conference. "Epidemiology of heart disease and hypertension in African Americans." Orlando, Florida, November 8, 1997.

16. "Managing cardiovascular risk in African-Americans." Presented at the First Conference on Cardiovascular Health: Coming together for the 21st century. San Francisco, California, February 19, 1998.

17. "Microalbuminuria in minority populations." Presented at National Kidney Foundation (NKF) Consensus Conference on Proteinuria, Nashville, Tennessee, March 25-26, 1998.

18. "Hypertension in blacks." Presented at the World Cardiology Congress, Rio de Janeiro, Brazil, April 30, 1998.

19. "Salt and cardiovascular disease: implications for African Americans." Third Congress on Treatment of Cardiovascular Disease in African Americans, Presented at the American Heart Association, Dallas, Texas, November 10, 1998.

20. "Difficult to treat patient populations and the identification of individual treatment needs." New Therapeutic Goals in Hypertension. Presented at the American Heart Association, Dallas, Texas, November 7, 1998.

21. Keynote speaker, DMC Heart Academy's First Annual Scholarship Banquet, McGegor Memorial Hall, Detroit, Michigan, November 14, 1998.

22. "Impact of smoking on the CVD-Renal system." Wayne State University Smoking and Interdisciplinary Research Breakfast and Conference, Karmanos Cancer Institute, Detroit, Michigan, November 19, 1998.

23. "Can the treatment of hypertension prevent sudden death in athletes?" Presented at the John B. Johnson Memorial Lecture and Dinner Gala, Las Vegas, Nevada, August 9, 1999.

24. Regional Differences in Cardiovascular Disease. "Does ethnicity play a role?" Presented at the American Heart Association 72nd Scientific Session, Atlanta, Georgia, November 8, 1999.

25. Hypertension management in special populations and conditions. "African Americans." Presented at the American Heart Association 72nd Scientific Session, Atlanta, Georgia, November 8, 1999.

26. 16th Annual International Society on Hypertension in Blacks (ISHIB). "Aldosterone: "a cardiovascular risk hormone and its importance in hypertension." Las Vegas, Nevada, July 10-15, 2000.

27. 4th Annual Scientific meeting (HFSA). "Racial differences in response to heart failure therapy". Boca Raton, Florida, Sept 10-13, 2000.

28. National Kidney Disease Education Program. "Screening and kidney early evaluation and prevention program" (KEEP). Natcher Conference Center, NIH Campus, Bethesda, Maryland, March 16, 2001.

29. 2nd International meeting of the International Federation of Kidney Foundation (IFKF). "Association between proteinuria, renal disease and morbidity and mortality. South Los Angeles, California, October 18-20, 2001

30. Hahemann University Hospital-MCP Hahnemann University School of Medicine, Department of Medicine. "Isolated systolic hypertension (Hypertension in the elderly). Philadelphia, Pennsylvania, December 12, 2001.

31. Annual International Society on Hypertension in Blacks (ISHIB). "Reversing the cardiovascular disease epidemic among ethnic minority populations: Translating strategies into success. Miami, Florida, June 8-12, 2002.

32. First International Summit on Kidney Disease Prevention Scientific Meeting of the National Kidney Foundation Singapore. "Primary prevention of renal disease and related chronic disease theoretical basis/clinical evidence. Singapore, July 23-27, 2002.

33. American Society of Nephrology, Treatment of hypertension in special populations: "Hypertension and African Americans: are they a special population"? Philadelphia, Pennsylvania, October 30-November 4, 2002.

34. Michigan Department of Health "Cardiovascular drug therapy, which drug for which patient." Detroit, Michigan, July14 2003.

35. General Motors (GM) Corporation – 2003 GMAAN All People Meeting, panel discussion on "Hypertension" to GM employees. Warren, Michigan, October 27, 2003.

36. Annual Honor's Convocation Langston University, Keynote address "A legacy of leadership" to students who have demonstrated leadership and academically excelled. Langston, Oklahoma, April 8, 2004.

37. Henry Clark Stroke Foundation "Hypertension". Cobo Hall Arena, Detroit, Michigan, May 8, 2004.

38. 19th Annual International Society on Hypertension in Blacks (ISHIB). "Disparities in cardiovascular disease: bridging the great divide", Detroit, Michigan, June 13-16, 2004.

39. 6th Annual International Fatherhood Conference, "The silent killer of men". Detroit, Michigan, June 17, 2004.

40. The Michigan Consortium for Minority Health and Academic Development, Keynote Address "Racial and ethnic Disparities: The looking glass into broader societal and health system problems", Detroit, Michigan, September 29, 2004.

41. Wayne State University School of Medicine, Michigan Department of Community Health. "Health Disparities" Lansing, Michigan, January 18, 2005

42. Henry Ford Hospital Cardiology Grand Rounds. "Benefits of Aldosterone Blockers for Hypertensive Patients". Detroit, Michigan, January 26, 2005.

43. Wayne State University Lecture. "Center for Urban and African American health and disparities related research". Detroit, Michigan, February 7, 2005

44. Wayne State University Department of Medicine Faculty. "Center for Urban and African American (CUAAH) Grant Initiative". Detroit, Michigan, February 21, 2005.

45. Detroit Medical Society "Hypertension & Lipids", Detroit, Michigan, February 23, 2005.

46. 54th Annual Scientific Session, ACC. Co-Chair "Ethnic Disparity: optimizing therapy across patient populations" session, Orlando, Florida, March 6-9, 2005.

47. Wayne State University College of Nursing Research Day, "Center for Urban and African-American Health (CUAAH): A multidisciplinary approach to complex research questions", Detroit, Michigan, March 23, 2005.

48. Boehringer Ingelheim Speaker Series. "Treating the difficult hypertension patient", Southbend, Indiana, April 7, 2005

49. Boehringer Ingelheim Speaker Series. "Treatment of Hypertension", Fort Wayne Indiana, April 8, 2005.

50. Joint ASH/ISHIB Special Symposium. "Hypertension and Dyslipidemia: Dual therapy in cardiovascular disease risk reduction" San Francisco, California May 14, 2005

51. Henry Ford Wyandotte Grand Rounds. "Hypertension", Wyandotte, Michigan, May 26, 2005.

52. Novartis Speaker Meeting. "Strategies for managing hypertension", Kalamazoo, Michigan, May 26, 2005.

53. ISHIB 2005 Scientific Program, "Hypertension diagnosis, risk stratification and basic therapeutic principles" and "Hypertension in African Americans: A state of the art lecture" San Juan, Puerto Rico, July 13, 2005

54. Henry Ford Wyandotte Hospital – Cardiology Fall Symposium, "Hypertension", Wyandotte, Michigan, September 7, 2005

55. Maya Angelou Research Center, 2005 National Conference on CVD Disparities: Translating Research into Practice, "Unraveling the tangled web of race, genes, disease, and therapeutics" Winston-Salem, North Carolina, September 9, 2005

56. Case Western Reserve University – Health Disparities: from Genetics to Health Policy Symposium, "Health Disparities and Hypertension" Cleveland, Ohio, September 2006.

57. MLK Distinguished Visiting Professor Grand Rounds Duke University Medical Center, "The genesis of cardiovascular-renal diseases in African-Americans: New insights into unanswered questions and unquestioned answers," Durham, North Carolina, January 19, 2007

58. General Motors Corporation Black History Month Guest Speaker, "African-American Health Initiatives" February 23, 2007

59. Wayne State University Ambulatory Grand Rounds. "managing hypertension in ambulatory settings: The basics, common problems, and cardinal rules" March 6, 2007

60. GRAAH I Medical Grand Rounds, "Meeting the challenge of treating hypertension in diabetes mellitus: Challenges and opportunities for better blood pressure control" Grand Rapids, Michigan, May 30, 2007

61. International Society of Hypertension in Blacks 2007 Annual Meeting. "Clinical Trials in Endothelial Disease State Progression" Orlando, Florida, June 22, 2007

62. CRAIN Medical Grand Rounds Cleveland Clinic, "Ruminations Regarding the excess cardiovascular-renal disease burden in U.S. Blacks: Clues from interlinked deranged physiological pathways" Cleveland, Ohio, July 26, 2007

63. SUNY Downstate Medicine Grand Rounds, "Hypertension in African-Americans" Brooklyn, New York, April 10, 2008

64. UNC Medicine Grand Rounds, "Dietary cation intake and vitamin d deficiency as plausible mediators of excess cardiovascular diseases in Blacks" Chapel Hill, North Carolina, April 17, 2008

65. International Society of Hypertension in Blacks 23rd Annual Interdisciplinary Conference, "Commonly encountered problems in hypertension therapeutics" New Orleans, Louisiana, July 20, 2008

66. Association of Black Cardiologists, Dr. Walter M Booker, Sr. Memorial Symposium, The Inaugural Elijah B. Saunders Memorial Lecture; "Treatment of Resistant Hypertension: Current status and new innovations" Orlando, Florida, November 7, 2015

BOOKS REVIEWED

1. Black Man in a White Coat, by Damon Tweedy, MD; Chicago Tribune, Oct. 1, 2015

FLACK

EXHIBIT B

In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 19-2875

JOHN M. FLACK, M.D., MPH
LIST OF MATERIALS CONSIDERED

MATERIALS CONSIDERED	BATES NOS.
MDL PLEADINGS AND GENERAL DOCUMENTS	
2019.06.17 Am. Master Personal Injury Complaint	N/A
2019.06.17 Am. Master Medical Monitoring Complaint	N/A
2020.03.13 Am. Master Economic Monitoring Complaint	N/A
2019.06.26 Confidentiality and Protective Order	N/A
2021.02.11 0870 - Letter from Lori G. Cohen to Judge Vanaskie – overview	N/A
2021.02.11 0871 - Letter from Adam Slater to J. Vanaskie - overview	N/A
2020.12.18 0679 - Amended Complaint - Economic Class - Losartan	N/A
2020.12.18 0681 - Amended Complaint - Medical Monitoring Class Action Complaint - Master Losartan	N/A
2020.12.18 0682 - Amended Complaint - Personal Injury Complaint - Master Losartan	N/A
2021.01.15 0751 - 1st Amended Consolidated Losartan Class Action Complaint	N/A
WRITTEN DISCOVERY	
2020.12.31 - Plaintiffs' Disclosure of Cancer Types	N/A
DEPOSITION TRANSCRIPTS (WITH EXHIBITS)	
Raphael Nudelman – 04.08.2021 - Transcript	N/A
79 - Notice of Deposition	N/A
80 - Response to Plaintiffs' Document Requests	N/A
81 - Resumé Raphael Nudelman, Ph.D., ERT	TEVA-MDL2875-DEPS-000019-24
82 - LinkedIn Raphael Nudelman, Ph.D., ERT	TEVA-MDL2875-DEPS-000025-26
83 - No Exhibit	No Exhibit
84 - No Exhibit	No Exhibit
85 - Audit Report On ZHP (Chuannan Site) 9/2/11	TEVA-MDL2875-00051288
86 - No Exhibit	No Exhibit
87 - Auditing of API Manufacturers 3/27/12	TEVA-MDL2875-00102747
88 - E-mail, 7/4/12 Subject, Genotoxicity Evaluation for Valsartan (Azide Route)	TEVA-MDL2875-00539802
89 - Computational Toxicology Report for Valsartan Reagents and Intermediates 7/19/12	TEVA-MDL2875-00259857
90 - E-mail Thread 8/1/12 Subject, Acetaldehyde Toxicity	TEVA-MDL2875-00514864-66
91 - No Exhibit	No Exhibit
92 - No Exhibit	No Exhibit
93 - E-mail Thread 3/30/14 Subject, Amlodipine Besilate	TEVA-MDL2875-00158436-39
94 - Caspofungin 50-70 mg Powder for Concentrate For Solution for Infusion 3.2.P.2	TEVA-MDL2875-00917440-19

95 - Computational Mutagenicity Report For Potential Impurity In Valsartan 10/14/15	TEVA-MDL2875-00259986-87
96 - E-mail Thread 6/15/16 Subject, Toxicology of Hydrolyzed Calpronium Chloride	TEVA-MDL2875-00158463-69
97 - No Exhibit	No Exhibit
98 - E-mail Thread 12/19/17 Subject, Valsartan Proposal for API Specifications Revision US	TEVA-MDL2875-00082321-24
99 - Computational Mutagenicity and Control Recommendations For Potential Impurities In Valsartan	TEVA-MDL2875-00158698-05
100 - Quality Risk Management for Cross Contamination Control	TEVA-MDL2875-00260122
101 - E-mail Thread 6/28/18 Urgent and Important Genotoxic Impurity Notification	TEVA-MDL2875-00056559-61
102 - Request for Safety Assessment of NDMA for Valsartan Dose 1x Daily for 320mg, 160mg, 80mg (June 28, 2018)	TEVA-MDL2875-00425812-14
103 - Toxicological Assessment for NDMA In Valsartan Drug Substance 6/29/18	TEVA-MDL2875-00158529
104 - No Exhibit	No Exhibit
105 - E-mail Thread 7/3/18 Subject, Urgent Valsartan Safety Assessment Request	TEVA-MDL2875-00158519-22
106 - E-mail Thread 7/4/18 Subject Valsartan Urgent	TEVA-MDL2875-00056924-29
107 - E-mail Thread 7/4/18 Subject, Valsartan Urgent	TEVA-MDL2875-00514896-02
108 - E-mail Thread 7/4/18 Subject, Valsartan Urgent	TEVA-MDL2875-00020609-18
109 - E-mail Thread 7/5/18 Subject, Valsartan Urgent	TEVA-MDL2875-00158540-41
110 - E-mail Thread 7/5/18 Subject, Valsartan Urgent	TEVA-MDL2875-00495085
111 - E-mail Thread 7/5/18 Subject, Valsartan HHA draft V3 for Review	TEVA-MDL2875-00057083-85
112 - No Exhibit	No Exhibit
113 - No Exhibit	No Exhibit
114 - Draft HHA Valsartan Tablets 40, 80, 160, 320 Multiple Lots	TEVA-MDL2875-00057086-94
115 - No Exhibit	No Exhibit
116 - E-mail Thread 7/12/18 Subject, Valsartan	TEVA-MDL2875-00158544
117 - E-mail Thread 7/13/18 Subject, Valsartan Request from Hong Kong	TEVA-MDL2875-00540426-30
118 - E-mail Thread 7/13/18 Subject, EDQM Valsartan Provisional Limit Potential Impact on HHAs	TEVA-MDL2875-00021077-78
119 - Certification of Substances Department 8/10/18 Request for Information Relating to EU Referral Article 31 of Directive 2001/83/EC	N/A
120 - No Exhibit	No Exhibit
121 - E-mail Thread 9/6/18 Subject, Draft Valsartan Letter	TEVA-MDL2875-00552854-59
121A - NDMA Acceptable Limit (Handwritten Document From Plaintiff's Counsel Watt)	N/A
122 - E-mail Thread 10/22/18 Subject, NDMA & NDEA Limits	TEVA-MDL2875-00514942-43
123 - No Exhibit	No Exhibit

124 - E-mail Thread 12/27/18 Subject, Update 26th December 2018 RV Update	TEVA-MDL2875-00540783-88
125 - No Exhibit	No Exhibit
126 - E-mail Thread 3/26/19 Subject, Snodin & Elder Commentary	TEVA-MDL2875-00492386
127 - E-mail Thread 6/27/19 Subject, Request to be An Honorable Keynote Speaker	TEVA-MDL2875-00540844-46
128 - E-mail Thread 8/11/19 Subject, Editor's Spotlight Switzerland	TEVA-MDL2875-00158591-93
129 - Questionnaire for Excipient Nitrosamines Risk Evaluation	TEVA-MDL2875-00158603-09
130 - E-mail Thread 10/23/19 Subject, Ranitidine NDMA Formation	TEVA-MDL2875-00562588-97
131 - No Exhibit	No Exhibit
132 - No Exhibit	No Exhibit
133 - HHA Valsartan Tablets 40, 60,160, 320 mg Multiple Lots	TEVA-MDL2875-00274341-49
134 - Toxicological Assessment for NDMA And NDEA in Parallel in Sartan-Drug Substances	TEVA-MDL2875-00773542
EXPERT REPORTS (WITH EXHIBITS)	
Plaintiffs' Expert Reports (with Exhibits)	
2021.07.04 Dr. Mahyar Etminan Report	N/A
2021.05.00 Dr. Mahyar Etminan CV	N/A
2021.07.06 Dr. Stephen Hecht Report	N/A
2021.07.06 Dr. Stephen Hecht CV	N/A
2021.07.06 Dr. Stephen Hecht Documents Reviewed	N/A
2021.07.06 Dr. Stephen Hecht Literature References	N/A
2021.07.06 Dr. Stephen Lagana Report	N/A
2021.04.05 Dr. Stephen Lagana CV	N/A
2021.07.07 Dr. David Madigan Report	N/A
2021.06.01 Dr. David Madigan CV	N/A
2021.07.06 Dr. Dipak Panigrahy Report	N/A
2021.07.00 Dr. Dipak Panigrahy CV	N/A
TEVA DOCUMENTS	
2017.12 – 2017.03 Annual Product Review for Valsartan, 40 mg, 80 mg, 160 mg, and 320 mg Tablets	TEVA-MDL2875-00828411
2018.06.29 Teva Toxicological Assessment of NDMA impurity in valsartan by Dr. Nudelman	TEVA-MDL2875-00414029
2018.06.29 Teva Toxicological Assessment of NDMA impurity in valsartan by Dr. Nudelman	TEVA-MDL2875-00274358
2018.07.06 Teva Health Hazard Assessment re Valsartan	TEVA-MDL2875-00329227-34
2018.07.06 Teva Health Hazard Assessment re Valsartan	TEVA-MDL2875-00274341
2018.07.06 Teva Health Hazard Assessment re Valsartan/HCTZ	TEVA-MDL2875-00274351
2018. 07.10 Health Hazard Assessment, Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) Tablets, 5/160/12.5 mg, 5/160/25 mg, 10/160/12.5 mg, 10/160/25 mg, and 10/320/25 mg, Multiple Lots	TEVA-MDL2875-00680244
2018.07.10 Health Hazard Assessment, Amlodipine and Valsartan Tablets, 5/160 mg, 10/160 mg, 5/320 mg, and 0/320 mg, Multiple Lots	TEVA-MDL2875-00680243

2018.11.12 Tox Assessment for NDEA in Valsartan by Dr. Nudelman	TEVA-MDL2875-00953115
2018.11.14 Toxicological Assessment for N-Nitrosodiethylamine (NDEA) in Valsartan Drug Substance	N/A
2018.11.19 Teva Health Hazard Assessment re NDEA in Valsartan Containing Drugs	TEVA-MDL2875-00414019-26
2018.11.19 Teva Health Hazard Assessment re NDEA in Valsartan Containing Drugs	TEVA-MDL2875-00426004
2019.03.13 Tox Assessment for NDMA and NDEA in Sartan Drugs in Parallel	TEVA-MDL2875-00773542
2019.07.03 Teva Risk Assessment Report for Valsartan Huahai	TEVA-MDL2875-00693424
2019.07.03 Teva Risk Assessment Report for Valsartan Mylan	TEVA-MDL2875-00693422
2019.07.18 Teva Valsartan Analytical Drug Substance & Drug Product Testing Results	TEVA-MDL2875-00063060
ZHP root cause	TEVA-MDL2875-00783229
Mylan root cause	TEVA-MDL2875-00019995
FDA/REGULATORY GUIDANCES AND DOCUMENTS	
Publicly Available FDA Documents	
2012.09.21 FDA approves first ANDA for generic valsartan (ANDA#078020)	N/A
2018.07.13 FDA Announces Voluntary Recall, FDA News Release	N/A
2018.07.17 Teva Issues Voluntary Recall	N/A
2018.07.18 Recalled US Valsartan Labels	N/A
2018.08.30 FDA Statement on Ongoing Investigation into Valsartan Impurities	N/A
2018.10.02 Laboratory analysis of valsartan products	N/A
2018.10.11 FDA – Combined Direct Injection NDMA and NDEA Impurity Assay by GC/MS	N/A
2018.10.16 FDA - Combined Direct Injection NDMA and NDEA Impurity Assay by GC/MS	N/A
2018.11.27 Teva Announces Voluntary Recall of All Amlodipine	N/A
2019.04.04 FDA Statement – Update on Recall	N/A
2019.04.15 Laboratory analysis of valsartan products	N/A
2019.06.13 Valisure Citizens Petition	N/A
2020.10.02 FDA Overview of Guidance for Industry	N/A
2020.12.04 Laboratory analysis of valsartan products - FDA	N/A
LITERATURE	
ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension 2018;71:e13-e115. DOI:10.1161/HYP.0000000000000065.	N/A
Adamson, RH, Chemical carcino-genesis in non-human primates. In:Longenbach R, Nesnow S, Rice JM, eds. Organand Species Specificity in Chemical Carcinogene-sis, New York and London: Plenum Publishing Corp. 129–156 (1983)	N/A
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Yoon, H., et al, "Risk of Cancer Following the Use of NNitrosodimethylamine (NDMA) Contaminated Ranitidine Products: A Nationwide Cohort Study in South Korea," J. of Clinical Med. (2021)	N/A
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Zheng, J, et al., Supplemental Table 1 to Dietary N-nitroso compounds and risk of pancreatic cancer: Results from a large case-control study (2019)	N/A
Zhu, Y, et al., Dietary N-nitroso compounds and risk of colorectal cancer (2014)	N/A
POST-MARKETING PERIODIC SAFETY REPORTS	
ANDA 077530 Valsartan Tablets 40 mg, 80 mg, 160 mg, 320 mg	
Teva Pharmaceuticals, 01 April 2015 – 30 June 2015	N/A
Teva Pharmaceuticals, 04 January 2016 – 03 April 2016	N/A
Teva Pharmaceuticals, 04 April 2016 – 03 July 2016	N/A
Teva Pharmaceuticals, 04 July 2016 – 03 October 2016	N/A
Teva Pharmaceuticals, 04 October 2016 – 03 January 2017	N/A
Teva Pharmaceuticals, 01 January 2017 – 31 March 2017	N/A
Teva Pharmaceuticals, 01 April 2017 – 30 June 2017	N/A
Teva Pharmaceuticals, 01 July 2017 – 30 September 2017	N/A
Teva Pharmaceuticals, 01 October 2017 – 31 December 2017	N/A
Teva Pharmaceuticals, 01 January 2018 – 31 March 2018	N/A
Teva Pharmaceuticals, 01 April 2018 – 30 June 2018	N/A
Teva Pharmaceuticals, 01 July 2018 – 30 September 2018	N/A
Teva, 01 October 2017 – 31 December 2018	N/A
ANDA 090642 Valsartan Tablets 40 mg, 80 mg, 160 mg, 320 mg	
Watson Laboratories, 05 January 2015 – 04 April 2015	N/A
Watson Laboratories, 05 April 2015 – 04 July 2015	N/A
Watson Laboratories, 05 July 2015 – 04 October 2015	N/A
Watson Laboratories, 05 October 2015 – 04 January 2016	N/A
Watson Laboratories, 05 January 2016 – 04 April 2016	N/A
Watson Laboratories, 05 April 2016 – 04 July 2016	N/A
Watson Laboratories, 05 July 2016 – 04 October 2016	N/A
Teva Pharmaceuticals, 05 October 2016 – 04 January 2017	N/A
Teva Pharmaceuticals, 05 January 2017 – 04 April 2017	N/A
Teva Pharmaceuticals, 05 April 2017 – 04 July 2017	N/A
Teva Pharmaceuticals, 05 July 2017 – 04 October 2017	N/A
Teva, 01 January 2018 – 31 December 2018	N/A
ANDA 091235 Amlodipine and Valsartan Tablets 5/160 mg, 10/160 mg, 5/320 mg, 10/320 mg	
Teva Pharmaceuticals, 01 June 2015 – 31 August 2015	N/A
Teva Pharmaceuticals, 01 September 2015 – 30 November 2015	N/A
Teva Pharmaceuticals, 01 December 2015 – 29 February 2016	N/A
Teva Pharmaceuticals, 01 March 2016 – 31 May 2016	N/A
Teva Pharmaceuticals, 01 June 2016 – 31 August 2016	N/A
Teva Pharmaceuticals, 01 September 2016 – 30 November 2016	N/A
Teva Pharmaceuticals, 01 December 2016 – 28 February 2017	N/A
Teva Pharmaceuticals, 01 March 2017 – 31 May 2017	N/A

Teva Pharmaceuticals, 01 December 2017 – 28 February 2018	N/A
Teva, 01 March 2018 – 28 February 2019	N/A
ANDA 091519 Valsartan and Hydrochlorothiazide Tablets 80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg, 320/25 mg	
Watson Laboratories, 21 March 2013 – 20 June 2013	N/A
Watson Laboratories, 21 June 2013 – 20 September 2013	N/A
Watson Laboratories, 21 September 2013 – 20 December 2013	N/A
Watson Laboratories, 21 December 2013 – 20 March 2014	N/A
Watson Laboratories, 21 March 2014 – 20 June 2014	N/A
Watson Laboratories, 21 June 2014 – 20 September 2014	N/A
Watson Laboratories, 21 September 2014 – 20 December 2014	N/A
Watson Laboratories, 21 December 2014 – 20 March 2015	N/A
Watson Laboratories, 21 March 2015 – 20 June 2015	N/A
Watson Laboratories, 21 June 2015 – 20 September 2015	N/A
Watson Laboratories, 21 September 2015 – 20 December 2015	N/A
Watson Laboratories, 21 December 2015 – 20 March 2016	N/A
Teva Pharmaceuticals, 21 March 2016 – 20 March 2017	N/A
Teva Pharmaceuticals, 21 March 2017 – 20 March 2018	N/A
ANDA 200435 Amlodipine, Valsartan and Hydrochlorothiazide Tablets 5/16012.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, 10/320/25 mg	
Teva Pharmaceuticals, 01 December 2014 – 28 February 2015	N/A
Teva Pharmaceuticals, 01 March 2015 – 31 May 2015	N/A
Teva Pharmaceuticals, 01 June 2015 – 31 August 2015	N/A
Teva Pharmaceuticals, 01 September 2015 – 30 November 2015	N/A
Teva Pharmaceuticals, 01 December 2015 – 29 February 2016	N/A
Teva Pharmaceuticals, 01 September 2016 – 30 November 2016	N/A
Teva Pharmaceuticals, 01 September 2017 – 31 August 2018	N/A
BELLWETHER PLAINTIFFS	
Bonmon, Yolanda	
Plaintiff Fact Sheet	
Plaintiff Fact Sheet, 04/28/2021	YBonmon-PFS-000001 – 748
Medical Records	
Plaintiff Produced Records	YBonmon-PPR-000001 – 658
Apothecare Pharmacy III	YBonmon-ApothPIII-000001 – 13
Bluegrass Women's Healthcare	YBonmon-BlueWHC-000001 – 59
Central Medical Associates PLLC	YBonmon-CMA-000001 – 267
Embry Charles, MD	YBonmon-CEmbry-000001 – 88
Hardin Memorial Hospital	YBonmon-HMH-000001 – 521
Laboratory Corporations of America	YBonmon-LCA-000001 – 7
Lincoln Trail Diagnostics	YBonmon-LTD-000001 – 52
Norton Cancer Institute	YBonmon-NCI-000001 – 11
Norton Healthcare	YBonmon-NortonHealthcare-000001 – 559

UK Albert B. Chandler Hospital	YBonmon-UKABCH-000001 – 162
Walgreen Company	YBonmon-WC-000001 – 9
Deposition	
Bonmon, Yolanda – 2021.04.20 – Transcript	N/A
1 – 2021.04.16 Plaintiff Fact Sheet	N/A
2 – 2021.04.16 Signed Declaration of Plaintiff Fact Sheet	N/A
3 – Photograph of Valsartan Bottle	YBonmon-PPR-000319
4 - 2019.06.17 Amended Complaint - Master Personal Injury Complaint	N/A
5 – 2020.07.21 Bonmon Short Form Complaint	N/A
6 – Bonmon Medical Records from Charles K. Embry, MD	YBonmon-CEmbry-000001 – 88
7 – Bonmon Pharmacy Records from Apothecare Pharmacy	YBonmon-ApothPIII-000001 – 13
8 – Bonmon Medical Records from Bluegrass Women's Healthcare	YBonmon-BlueWHC-000001 – 55
9 – Bonmon Medical Records from Central Medical Associates	YBonmon-CMA-000035 – 89
10 – Bonmon Medical Record from UK Healthcare	YBonmon-PPR-000030
11 – Bonmon Medical Records from Central Medical Associates	YBonmon-CMA-000035 – 89
12 – Bonmon Medical Records from Central Medical Associates	YBonmon-CMA-000001 – 34
13 – Bonmon Medical Records from Hardin Memorial Hospital	YBonmon-HMH-MD-000019 – 480
14 – Bonmon Medical Records from Charles K. Embry, MD	YBonmon-CEmbry-000001 – 88
15 – 2021.04.16 Plaintiff Fact Sheet	N/A
16 – Bonmon executed authorization for New Hope Foster Agency	N/A
17 – Bonmon records from New Hope Foster Homes, Inc.	YBonmon-NHFAFC-HR-000001
18 – Bonmon Executed Tax Authorization	N/A
Weygandt, Robert	
Plaintiff Fact Sheet	
2020.04.07 Plaintiff Fact Sheet	RWeygandt-PFS-000267-000355
Medical Records	
Plaintiff-Produced Medical Records	RWeaygandt-PPR-001547-001817
Abrams Royal Pharmacy II Pharmacy	RWeygandt-ARPharmII-000001-000002
Advanced Imaging Center	RWeygandt-AImagingCe-000001-83
Aetna US Healthcare Legal Support Svcs	RWeygandt-AUSH-000001-000013
Baylor Regional Med Ctr at Plano Med Recs Dept	RWeygandt-BRMCP-MD-000001-000307
Baylor Regional Med Ctr at Plano Path Dept	RWeygandt-BRMCP-PD-000001-000001
Baylor Scott and White Health Rad Dept	RWeygandt-BSW-RD-000001-000002
Baylor Scott and White Health - NRS	RWeygandt-BSW-PD-000001-000001
Baylor Scott and White Health Med Recs Dept	RWeygandt-BSW-MD-000001-000002
Baylor Scott and White Health	RWeygandt-BSW-BD-000001-17
Baylor Surgicare at Plano Patient Accts	RWeygandt-BSPlano-BD-000001-000002

Baylor Surgicare at Plano - NR Radiology Cert	RWeygandt-BSPlano-RD-000001
Blue Cross Blue Shield of Texas Claims Dept	RWeygandt-BCBST-000001-000048
Carrell Clinic - Medical	RWeygandt-CarrellC-000001-000057
Clinical Path Labs Inc	RWeygandt-CPL-000001-000004
Colon And Rectal Assocs of Texas	RWeygandt-C&RAT-000001-000027
Death Certificate Proof Of Authority	RWeygandt-DCPOA-000001-000004
DFW Smiles	RWeygandt-DFWS-000001-000018
Endocrine Assocs of Dallas	RWeygandt-EAD-000001-000342
Express Scripts Inc Recs	RWeygandt-ES-000001-000021
Fleshman James Jr MD	RWeygandt-JFleshamnJr-000001-000219
Heart Hosp Baylor Plano Med Recs Dept	RWeygandt-HHBP-MD-000001-000657
Hollabaugh, Eric, MD - Medical	RWeygandt-EHollabaugh-000001-000008
Lab Corp of America Med Recs Dept	RWeygandt-LabCorpA-MD-000002-000009
Legacy Heart Ctr Med Recs Dept	RWeygandt-LHC-MD-000001-000001
Med Ctr of Plano Med Recs Dept	RWeygandt-MCPlano-MD-000001-000122
Med Ctr of Plano Rad Dept	RWeygandt-MCPlano-RD-000001-000001
Med Ctr of Plano Path Dept	RWeygandt-MCPlano-PD-000001-000002
Med Clinic of North Texas PA	RWeygandt-MCNT-000001-000093
North Central Surgical Ctr	RWeygandt-NCSC-000001-000250
North Point Lab	RWeygandt-NPL-000001-000001
Plano Dermatology Assocs	RWeygant-PDA-000001-000003
Quest Diagnostics Irving	RWeygandt-QD-Irving-000001-000002
Safeway Inc Corporate Pharmacy Dept	RWeygandt-Safeway-000001-000017
Texas Health Presbyterian Hosp Dallas Patient Accts	RWeygandt-THPHD-BD-000001-000009
Texas Health Presbyterian Hosp Dallas Path Dept	RWeygandt-THPHD-PD-000001-000001
Texas Health Presbyterian Hosp Dallas Rad Dept	RWeygandt-THPHD-RD-000001-000001
Texas Oncology Pharmacy Sammons	RWeygandt-TOPS-000001-000002
Texas Oncology Plano Prestonwood Med Recs Dept	RWeygandt-TO-PP-MD-000001-000391
TMI Sports Medicine and Orthopedic Surgery - NR Cert	RWeygandt-TMISMOS-000001-000001
Verity Cancer Center	RWeygandt-VCC-000001-56
VerityPET CT	RWeygandt-VPET-CT-000001-000065
Verity PET CT Rad Dept	RWeygandt-VPET-CT-RD-000001-000087
Walgreen Company	RWeygandt-WC-000001-000006
Deposition	
2021.04.13 Weygandt, Martha Transcript	
1 - Plaintiff's Fact Sheet	N/A
2 - Declaration	N/A
Composite 3 - Bankruptcy petition	N/A
3 - Motion for Setting and Request for Expedited Hearing on Motion to Use Cash Collateral	N/A
4 - Master Personal Injury Complaint	N/A
5 - First Amended Short Form Complaint	N/A
6 – Medical Records	N/A
7 - Death certificate	RWeygandt-DCPOA-000001
8 – Follow Up Examination	RWeygandt-PPR-000217-229
9 – Patient Tax / Insurance	RWeygandt-Safeway-0003-17
10 – Medical Records from Endocrine Associates of Dallas, P.A.	RWeygandt-EAD-000055-60

11 - Medical Records from W B Carrell Memorial Clinic	RWeygandt-CarrellC-000003-6
12 - Medical Records from Cardiology	RWeygandt-HHBP-MD-000431-433
13 - Medical Records from Endocrine Associates of Dallas, P.A.	RWeygandt-EAD-000074-78
14 – Medical Records Bates 1-16 with cover page	N/A
15 - Medical Records Bates 570-605	N/A
16 - Pharmacy Defendants' Exemplar Defendant Fact Sheet	N/A
Ramirez, Richard	
Medical Records	
Gerardo J. Franco, D.O., P.A.	RRamirez-GJFranco-000001-000003
Sylvester Comprehensive Cancer Center	RRamirez – SCCC-MD-000001-000616
University of Miami Hospital	RRamirez-UMHosp-MD-000001-000158
Jackson Health System	RRamirez-JHS-MD-000001-000549
Briones, Joe	
Plaintiff Fact Sheet	
2021.01.13 Plaintiff Fact Sheet	JBriones-PFS-000095-000187
Medical Records	
Plaintiff-Produced Medical Records	JBriones-PPR-000001-431
Aetna US Healthcare	JBriones-AUSH-000001-000118
Centers for Medicare and Medicaid Services	JBriones-CMMS-R6-000001-000505
Citizens Medical Center Patient Accounts	JBriones-CMCen-BD-000001-000017
Citizens Medical Center	JBriones-CMCen-MD-000001-407
Citizens Med Ctr Path Dept	JBriones-CMCen-PD-000001-0000002
Citizens Med Ctr Rad Dept	JBriones-CMCen-RD-000001-000003
Clinical Path Labs Inc Path Dept	JBriones-CPL-PD-000001-000001
Costco Wholesale	JBriones-CostcoW-000001-5
DeTar Hosp Navarro Path Dept	JBriones-DeTarH-N-PD-000001-000001
DeTar Hospital-Navarro	JBriones-DeTarH-N-MD-000001-436
DeTar Hosp Navarro Rad Dept	JBriones-DeTarH-N-RD-000001-000004
DeTar Hosp Navarro Med Recs Dept	JBriones-DeTarH-N-MD-000437-000492
Envision Pharmacies	JBriones-EnvisionP-000001-000002
Gastroenterology of Victoria	JBriones-GVictoria-000001-7
HEB Pharmacy Privacy Office	JBriones-HEBPharm-000001-000002
Humana Inc Attention Critical Inquiry Dept	JBriones-Humana-000001-000001
Leggett Richard H DO Med Recs Dept	JBriones-RHLeggett-000001-000001
Minocha Gulshan K MD	JBriones-GKMinocha-000001-000217
Mundy Construction Company HRs	JBriones-MCC-HR-000001-000378
Plaintiff Produced Records	JBriones-PPR-000001-000431
Regional Path Assocs Path Dept	JBriones-RPA-PD-000001-000002
Regional Path Assocs	JBriones-RPA-000001-000002
Sierra Hoffman Miguel MD	JBriones-MSierra-Hoffman-000001-000001
Univ of Texas MD Anderson Cancer Ctr Rad Dept	JBriones-UTMDACC-RD-000001-000039
Univ of Texas MD Anderson Cancer Ctr Path Dept	JBriones-UTMDACC-PD-000001-000002
Univ of Texas MD Anderson Cancer Ctr Patient Accts	JBriones-UTMDACC-BD-000001-000113
Univ of Texas MD Anderson Cancer Ctr Med Recs Dept	JBriones-UTMDACC-MD-000001-008520

Zachry Industrial Inc HRs	JBriones-ZI-HR-000001-000021
Dawson, Nellie	
Plaintiff Fact Sheet	
2020.05.14 Plaintiff Fact Sheet	NDawson-PFS-000092-000180
Medical Records	
Plaintiff-Produced Medical Records	NDawson-PPR-000001-000179
3HC Home Health Hospice Healthcare	NDawson-3HCHH-H-HC-000001-000114
Jordan And Assocs Gastroenterology PA	NDawson-J&AG-000001-000068
Riverdale Family Medicine PA	NDawson-RFM-000001-000332
UNC Health Care System Path Dept	NDawson-UNCHCS-PD-000001-000001
UNC HealthCare System Rad Dept	NDawson-UNCHCS-RD-000001-000001
Dufrene, Lana	
Plaintiff Fact Sheet	
Plaintiff Fact Sheet, 02/10/2021	LDufrene-PFS-000001 – 186
Medical Records	
Plaintiff Produced Records	LDufrene-PPR-000001 – 178
Cardiovascular Institute of the South	LDufrene-CIS-000001 – 183
Lady of the Sea General Hospital	LDufrene-LSGH-000001 – 77
Leonard J. Chabet Medical Center	LDufrene-LJCMC-000001 – 2271
Ochsner Family Doctor Clinic	LDufrene-OFDC-000001 – 193
Racelands Pharmacy	LDufrene-RPE-000001 – 13
Walmart Pharmacy	LDufrene-WMS-000001 – 20
Garcia, Robert	
Plaintiff Fact Sheet	
2021.03.10 Plaintiff Fact Sheet	RGarcia-PFS-000188-00280
Medical Records	
Plaintiff-Produced Medical Records	RGarcia-PPR-000001-000434
Baylor St Lukes Med Ctr Health Information Mgmt	RGarcia-BStLMC-MD-000001-000831
Baylor St Lukes Med Ctr Patient Accts	RGarcia-BStLMC-BD-000001-000040
Baylor St Lukes Med Ctr Rad Dept	RGarcia-BStLMC-RD-000001-000003
Blue Cross Blue Shield of Texas Recs Dept	RGarcia-BCBSTexas-000001-000004
Ctrs for Medicare and Medicaid Svcs Region 6 Legal Dept Privacy Office	RGarcia-CMMS-R6-000001-000017
Cigna Healthcare Central HIPPA Unit Legal Dept	RGarcia-CHCHU-000001-000064
City of Houston HRs	RGarcia-CHouston-HR-000001-000246
CVS Pharmacy Inc Privacy Office	RGarcia-CVS-000001-000025
Digestive Disease Consultants PA	RGarcia-DDC-000001-000001
Express Scripts Inc Records	RGarcia-ES-000001-000012
Harris County Psychiatric Ctr	RGarcia-HCPC-000001-000001
Harris County Psychiatric Ctr Patient Accts	RGarcia-HCPCenter-000001-000001
HEB Pharmacy Privacy Office	RGarcia-HEBPharm-000001-000025
Kelsey Pharmacy Berthelsen Main Campus	RGarcia-KelseyP-BMC-000001-000003
Kelsey Seybold Clinic	RGarcia-KSC-000001-001500
Kelsey Seybold Clinic Rad Dept	RGarcia-KSC-RD-000001-000002
Selzman Harold MD	RGarcia-HSelzman-000001-000002
Texas Digestive Disease Consultants	RGarcia-TexasDDC-000001-000042
Walgreen Company	RGarcia-WC-000001-000079
Walker Frank S Jr MD	RGarcia-FSWalkerJr-000001-000001

Walmart Pharmacy	RGarcia-WMS-000001-000010
Wellspire Med Group	RGarcia-WMG-000001-000001
Kennedy, Paulette	
Plaintiff Fact Sheet	
2021.06.17 Plaintiff Fact Sheet	PKennedy-PFS-000377-000469
Medical Records	
Plaintiff-Produced Medical Records	PKennedy-PPR-000001-000590
Baylor Scott And White Med Ctr McKinney Med Recs Dept	PKennedy-BS&WMC-M-MD-000001-000438
Baylor Scott & White Medical Center-McKinney	PKennedy-BS&WMC-M-BD-000001-12
Ctrs for Medicare and Medicaid Svcs Region 6 Legal Dept Privacy Office	PKennedy-CCMS-R6-000001-001371
Dallas Nephrology Assocs	PKennedy-DallasNephA-000001-000125
Eye Assocs of Tallahassee	PKennedy-EAT-000001-000085
Kroger Pharmacy Corporate HQ Legal Dept	PKennedy-KrogerPharm-000001-000009
Lajara Rosemarie MD	PKennedy-RLajara-000001-000010
Med City Dallas Hosp Patient Accts	PKennedy-MCDH-BD-000001-000080
Med City Dallas Hosp Med Recs Dept	PKennedy-MCDH-MD-000001-000453
Med City Dallas Hosp Rad Dept	PKennedy-MCDH-RD-000001-000005
North Star Diagnostic Imaging	PKennedy-NStarDI-000001-000033
North Star Diagnostic Imaging Rad Dept	PKennedy-NStarDI-RD-000001-000001
Orthopaedic Surgery and Sports Medicine of Dallas	PKennedy-OSSMD-000001-000119
Snyder Hopkins Family Medicine Ctr	PKennedy-S-HFMC-000001-000001
Solis Mammography	PKennedy-SolisM-000001-000034
Southern Endocrinology And Diabetes Assocs	PKennedy-SEndo&DA-000001-000033
Texas Breast Specialists	PKennedy-TBS-000001-168
Texas Colon And Rectal Surgeons	PKennedy-TC&RSurgeons-000001-000128
Texas Eye Plastics	PKennedy-TEyeP-000001-000021
Texas Health Family Care	PKennedy-TexasHFC-000001-000001
Texas Health Family Care Clinic 040	PKennedy-THFCC040-000001-000001
Texas Oncology	PKennedy-TOncology-000001-000385
Texas Oncology Patient Accts	PKennedy-TO-BD-000001-000053
Texas Oncology PA Rad Dept	PKennedy-TOncology-RD-000001-000002
United Healthcare Insurance AARP Claims Customer Svc	PKennedy-UHI-000001-000019
Walgreen Company	PKennedy-WC-000001-000091
Walton, William J., MD - NRS	PKennedy-WJWalton-000001-2
Winter John W IV MD	PKennedy-JWinterIV-000001-000001
Kinkela, Silvano	
Plaintiff Fact Sheet	
2021.06.10 Plaintiff Fact Sheet	SKinkela-PFS-000547-000639
Medical Records	
Plaintiff-Produced Medical Records	SKinkela-PPR-000216-000430
Aaron Jay S MD	SKinkela-JSAaron-000001-000085
Ctrs for Medicare And Medicaid Svcs	SKinkela-CMMS-R3-000001-000779
Costco Wholesale HIPAA Compliance	SKinkela-CostcoW-000001-000002
Kmart Pharmacy	SKinkela-KmartP-000001-2
Lackawanna Valley Dermatology Assocs	SKinkela-LVDA-000001-000019

Optum Rx	SKinkela-OptumRx-000001-000138
Pocono Ambulatory Surgery Ctr Rad Dept	SKinkela-PASC-RD-000001-000006
Pocono Med Ctr Patient Accts	SKinkela-PMC-BD-000001-000031
Pulmonary And Critical Care Specialists Med Recs Dept	SKinkela-P&CCS-MD-000001-000056
Rx Express Pharmacy	SKinkela-RxExpress-000001-000001
Sentara Leigh Hosp Med Recs Dept	SKinkela-SentaraLH-MD-000040-000262
Sentara Princess Anne Hosp Path Dept	SKinkela-SPAH-PD-000001-000001
Sentara Surgery Specialists	SKinkela-SSS-000424-000749
Sentara Virginia Beach General Hosp Path Dept	SKinkela-SVBGH-PD-000001-000001
St Lukes Univ Hosp Bethlehem Campus Patient Accts	SKinkela-SLUH-BC-BD-000001-000001
Urology Assocs ofThe Poconos	SKinkela-UAP-000001-000062
Village Family Medicine of Lionville	SKinkela-VFML-000001-000001
Virginia Oncology Assocs	SKinkela-VOA-000001-000093
Walgreen Company	SKinkela-WC-000001-000024
Lee, Robert	
Plaintiff Fact Sheet	
2020.12.23 Plaintiff Fact Sheet	RLee-PFS-000001-000167
Medical Records	
Plaintiff-Produced Medical Records	RLee-PPR-000001-000958
Blue Cross Blue Shield of South Carolina	RLee-BCBSSC-000001-000092
Ctrs for Medicare and Medicaid Svcs Region 4	RLee-CMMS-R4-000001-000126
Death Certificate Proof Of Authority	RLee-DCPOA-000001-000002
Family Healthcare Clinton	RLee-FH-C-000001-000404
Greenville Health System Patient Accts	RLee-GHS-BD-000001-000027
Greenville Health System Med Recs Dept	RLee-GHS-MD-000001-001985
Greenville Memorial Hosp Rad Dept	RLee-GMH-RD-000001-000017
Greenville Memorial Hospital -Billing	RLee-GMH-BD-000001-000005
Ingles Markets, Inc.	RLee-InglesM-000001-000029
Walmart Pharmacy	RLee-WMS-000001-000027
Meeks, Ronald	
Plaintiff Fact Sheet	
2021.01.15 Plaintiff Fact Sheet	RMeeks-PFS-000001-000288
Medical Records	
Plaintiff-Produced Medical Records	RMeeks-PPR-000001-006576
Central Arkansas Veterans Healthcare System Med Recs Dept	RMeeks-CAVHS-MD-000001-000011
Central Arkansas Veterans Healthcare System Path Dept	RMeeks-CAVHS-PD-000001-000002
Death Certificate Proof Of Authority	RMeeks-DCPOA-000001-000005
East Jefferson Cardiovascular Specialists Inc Med Recs Dept	RMeeks-EJCS-MD-000001-000163
East Jefferson General Hosp Path Dept	RMeeks-EastJGH-PD-000001-000001
East Jefferson General Hosp Med Recs Dept	RMeeks-EJGH-000751-002405
East Jefferson General Hosp Patient Accts	RMeeks-EastJGH-BD-000001-000027
East Jefferson General Hosp Rad Dept	RMeeks-EastJGH-RD-000001-000001
East Jefferson Internal Medicine	RMeeks-EJIM-000001-000057
Med Plaza ENT Physicians	RMeeks-MPENTP-000001-000036

Nola Discount Pharmacy Pharmacy	RMeeks-NDP-000001-000027
Ochsner Med Ctr Release of Information	RMeeks-OchsnerMC-MD-000001-003194
Ochsner Med Ctr Patient Accts	RMeeks-OchsnerMC-BD-000001-000124
Ochsner Med Ctr Kenner Med Recs Dept	RMeeks-OMC-K-MD-000001-000797
Ochsner Med Ctr Kenner Patient Accts	RMeeks-OMC-K-BD-000001-000010
Ochsner Med Ctr Kenner Path Dept	RMeeks-OMC-K-PD-000001-000001
Ochsner Med Ctr Kenner Rad Dept	RMeeks-OMC-K-RD-000001-000001
Ochsner Medical Complex - NR Cert Ltr	RMeeks-OMComp-000001-000001
Smith Kenneth B MD	RMeeks-KBSmith-000001-000175
Southeast Louisiana Veterans HealthCare System Rad Dept	RMeeks-SLVHCS-RD-000001-000062
Southeast Louisiana Veterans Health Care System	RMeeks-SLVHCS-RD-000008-000009
Tulane Univ Hosp and Clinic Rad Dept	RMeeks-TUHC-RD-000001-000003
Tulane Univ Hosp and Clinic Med Recs Dept	RMeeks-TUHC-MD-000001-000001
Univ Med Ctr New Orleans Rad Dept	RMeeks-UMCNO-RD-000001-000002
Univ Med Ctr New Orleans Patient Accts	RMeeks-UMCNO-BD-000001-000009
Univ Med Ctr New Orleans Path Dept	RMeeks-UMCNO-PD-000001-000001
Univ Med Ctr New Orleans Med Recs Dept	RMeeks-UMCNO-MD-000001-000389
Suits, James	
Plaintiff Fact Sheet	
Fifth Amended Plaintiff Fact Sheet, 02/03/21	JSuits-PFS-001131-1224
Medical Records	
Plaintiff-Produced Medical Records	JSuits-PPR-000001-001335
Aetna US Healthcare Legal Support Svcs	JSuits-AUSH-000001-000002
John Deere - NRS	JSuits-JohnDeere-HR-000001-000001
McCaysville Internal Medicine	JSuits-McCIM-000001-000251
Mutual of Omaha Insurance Company Claims Dept	JSuits-MOIC-000001-000003
Premier Surgical Assocs Cleveland	JSuits-PremierSAC-000001-000048
Tallent Drug Store	JSuits-TDS-000001-000036
Uhlik, Allen, MD	JSuits-AUhlik-000001-000383
MISCELLANEOUS	
All materials cited or referenced in my expert report and attachments	N/A
All materials cited in the reports of Drs. Mahyar Etminan, David Madigan, Stephen S. Hecht, Lagana, and Dipak Panigrahy and attachments	N/A
This list includes items Plaintiffs' experts relied upon. By so doing, Defendants and this expert are not waiving any arguments or objections related to admissibility.	N/A